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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

ALI ZAIDI, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. ADAMAS PHARMACEUTICALS, INC., GREGORY T. WENT, ALFRED G. MERRIWEATHER AND RICHARD A. KING, Defendants.	Case No. 4:19-cv-08051-JSW **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** **DEMAND FOR JURY TRIAL**

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Lead Plaintiff Ralph Martinez ("Plaintiff"), by his undersigned attorneys, hereby brings this Second Amended Class Action Complaint ("Complaint") against Adamas Pharmaceuticals, Inc. ("Adamas" or the "Company"), Gregory T. Went ("Went"), Alfred G. Merriweather ("Merriweather"), and Richard A. King ("King") (together, "Defendants"). The allegations herein are based on Plaintiff's personal knowledge as to his own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of Lead Counsel, which includes a review of: U.S. Securities and Exchange Commission ("SEC") filings by Adamas; securities analysts' reports and advisories about the Company; press releases and other public statements issued by the Company; media reports about the Company; interviews with former Adamas employees; and other publicly available information concerning Adamas. Lead Counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to, or are exclusively within the custody or control of, the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. On behalf of himself and the class he seeks to represent, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of persons or entities who or which purchased or acquired Adamas securities between August 8, 2017 and March 4, 2019, inclusive (the "Class Period") and who were damaged thereby, seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Adamas is a pharmaceutical company that specializes in developing treatments for chronic neurological disorders. It was formed by Went in 2000, who served as its CEO since Adamas' inception and throughout the Class Period. Adamas' success depended on successfully commercializing GOCOVRI, the first drug treatment Adamas developed and would market entirely on its own. GOCOVRI is an extended-release formulation of amantadine, for the treatment of levodopa-induced-dyskinesia ("LID"). Patients with Parkinson's disease are commonly treated with levodopa therapy to replace lost dopamine, which provides patients improved control over their

bodily movements. A common side effect from levodopa treatment is dyskinesia—involuntary and uncontrolled movements that occur when there is too much dopamine.

3. Amantadine had been prescribed to treat LID for decades and was available as a generic, but only in an immediate release formulation ("amantadine IR"). Amantadine IR is indicated for "the treatment of parkinsonism and drug-induced extrapyramidal reactions," which are "commonly referred to as drug-induced movement disorders," such as dyskinesia. However amantadine IR is not effective or tolerable for many patients, who often quit using it due to sleep related side effects. As a result, physicians typically adjusted the dose of levodopa rather than prescribe amantadine IR.

4. Adamas claimed that GOCOVRI would mitigate those sleep-related issues because it was administered once a day at nighttime, whereas the dosing for amantadine IR may be multiple times a day. By administering GOCOVRI at night, its concentration was at its highest during waking hours when dyskinesia was most bothersome, and would taper off at night, minimizing sleep issues.

5. During the Class Period, GOCOVRI's list price was $28,500 per year or $2,375 per month, whereas amantadine IR was available for a couple thousand dollars per year. Due to GOCOVRI's high cost and combined with amantadine IR's reputation for lacking efficacy and tolerability, GOCOVRI's commercial success was contingent on Adamas' ability to differentiate it from amantadine IR, such that it would gain the support of the patients, physicians, and payers (*i.e.*, health insurers and other managed care entities). Specifically, Adamas would have to show that GOCOVRI was more effective and more tolerable than amantadine IR, and was not merely a more convenient, yet more expensive, extended-release formulation of amantadine IR. Defendants acknowledged the importance of making this distinction and frequently discussed GOCOVRI's "value proposition." Payers' support was particularly critical given GOCOVRI's high cost, which necessarily required the ability of payers to differentiate GOCOVRI from amantadine IR. If payers could not differentiate the two, they would be less likely to provide reimbursement, or alternatively, would require expensive co-pays, and/or a showing of medical necessity, prior authorization, and/or

step-therapy, which would, in turn, suppress patient demand and physicians' willingness to prescribe GOCOVRI.

6. Efforts to differentiate GOCOVRI from amantadine IR, and thus, grow patient and physician demand, as well as payer support, were underway prior to and throughout the Class Period. However, Adamas faced a major hurdle because there was no head-to-head study comparing the two different formulations of amantadine. Moreover, existing studies of amantadine IR were not limited to treatment of LID, making differentiating GOCOVRI even more difficult for Adamas' potential patients, prescribers, and payers.

7. Nevertheless, throughout the Class Period, Defendants repeatedly told investors that patients, physicians, and payers were able to differentiate GOCOVRI from amantadine IR and understood its benefits. As such, investors were led to believe that payers would provide reimbursement support and physicians would prescribe GOCOVRI, thus painting a promising growth outlook for Adamas.

8. GOCOVRI was approved by the FDA on August 24, 2017 and was made available to patients in October 2017 and was fully commercially launched in January 2018 (the "launch"). Prior to launch, Adamas told investors that based on its communications with payers, they would provide reimbursement through medical necessity or prior authorization, but it did not anticipate that more burdensome requirement that patients first try, or "step-through,"[1] the generic amantadine IR. Contrary to Defendants' claims otherwise, as early as October 2017, payers were requiring step therapy, which was anticipated by the Company and accounted for in its forecasts.

9. Another obstacle to GOCOVRI's successful launch, was the Company's decision to exclusively distribute GOCOVRI through a specialty pharmacy, AllianceRx Walgreen's Prime, which also assisted patients with getting reimbursement through a program called GOCOVRI Onboard ("Onboard"). Adamas told investors that using a specialty pharmacy would allow them to provide a higher level of support to patients and that it had designed a simple Onboard prescription form with that would be easy for physicians to fill out. Nevertheless, Onboard's processes were not

[1] Also known as "step-therapy" or "step-edits."

familiar to the vast majority of patients and physicians (unlike the usual retail pharmacy processes most patients and physicians were used to); and therefore, Onboard's smooth operation was critical to GOCOVRI's success. Onboard's success also hinged on payer support for GOCOVRI – the more burdensome the requirements for reimbursement and the more frequent that reimbursement was denied, and appeals were processed, the more critical it was for Onboard to smoothly operate so physicians would not be frustrated by the process and stop writing prescriptions and patients would not drop-off.

10. In addition to assisting patients with obtaining reimbursement, Onboard provided a two-week sample of GOCOVRI while patients awaited payer reimbursement decisions through a program called QuickStart. This further increased the need for Onboard to quickly provide reimbursement, as patients and physicians would logically desire a consistent supply of GOCOVRI. The decision to use QuickStart was also a decision to forego providing physicians free samples, thus requiring physicians to write prescriptions and learn Onboard's processes. Without free samples, GOCOVRI's success hinged on physicians differentiating it from amantadine IR solely based on GOCOVRI's clinical data.

11. The importance of differentiating GOCOVRI from amantadine IR was exacerbated when the FDA granted approval for OSMOLEX ER ("OSMOLEX") in February 2018, just one month after GOCOVRI's commercial launch. OSMOLEX was an extended release version of amantadine, and was approved by the FDA for the same indication as amantadine IR using the same clinical data as amantadine IR. Moreover, OSMOLEX's list price was offered at a substantial discount to GOCOVRI and free samples were provided to physicians. Defendants publicly maintained that payers and physicians understood the value proposition of GOCOVRI and had already differentiated GOCOVRI from amantadine IR, and thus would view OSMOLEX as being the same as amantadine IR, and therefore, OSMOLEX did not pose a substantial threat to GOCOVRI's commercial success.

12. On the Company's May 9, 2018 earnings call, King acknowledged that some payers were "interested as to whether IR amantadine's been tried before in patients and has been shown to either be ineffective or not well tolerated[,]" but maintained that there was no "hard step" or "formal

step-through." For practical purposes, this was a distinction without a difference. Patients would need to make this showing, and if they were unable to do so, patients would be required to undergo a course of treatment with amantadine IR before reimbursement would be provided for GOCOVRI. Payer requirements that patients show whether amantadine IR has been tried and show to be either ineffective or not well tolerated prior to reimbursing a GOCOVRI prescription limited the available market for GOCOVRI, and also limited demand from physicians to those who were willing to undergo the additional burden of establishing that their patients met these step therapy requirements. It Moreover, early payer requirements to show unsuccessful amantadine IR use also sent a signal to other payers who had not yet made a coverage determination. Nevertheless, Defendants assured "we're not seeing that as a limitation to get access to GOCOVRI," knowing acknowledging that investors' concerns that such payer requirements would be concerned that this could negatively impact GOCOVRI's growth.

13. However, contrary to the Defendants claims, Adamas had not succeeded in differentiating itself from amantadine IR. Almost immediately after GOCOVRI was made available, payers began to restrict reimbursement of GOCOVRI pending an unsuccessful showing of amantadine IR use. And, as more payers evaluated the drug, more payers put in place reimbursement restrictions, including requiring step therapy, denying reimbursement, or providing low levels of reimbursement. Onboard also proved to be an operational disaster, frustrating physicians and patients. The two-week free supply provided through QuickStart was insufficient given the lengthy approval process, causing patients to drop-off. Demand was further stymied by the burdensome and lengthy approval process and high co-pays. Nevertheless, Defendants assured that payers were supporting GOCOVRI and maintained that reimbursement was happening through Onboard with ease and efficiency.

14. Exacerbating Adamas' demand woes, GOCOVRI's cost, and in combination with the lack of clinical data comparing GOCOVRI to amantadine IR and failure to provide physicians with free samples, meant that many physicians failed to appreciate its value proposition and were not willing to prescribe it. Moreover, many physicians and patients who did try GOCOVRI experienced the same tolerability issues with experienced with amantadine IR.

15. On October 5, 2018, Bank of America issued a report which partially revealed these issues with reimbursement and indicated that demand from physicians had weakened due to "hurdles" to get patients on GOCOVRI due prior authorization and step therapy requirements. On this news, Adamas' stock fell $1.52 per share, or 8%, on higher volume in early trading on October 5, 2018 to close at $17.83 per share on October 5, 2018, damaging investors.

16. The Company's failure to differentiate GOCOVRI for physicians and the corresponding impact on demand was partially revealed on November 1, 2018, when the Company announced that it was cutting the number or targeted physicians in half to focus on the movement disorder specialists and was "simplifying and strengthening our messaging …[to] effectively educat[e] physicians on appropriate use and appropriate patients for GOCOVRI."

17. The Company also announced on November 1, 2018 that the pace of prescription growth had flattened and projected it would only increase its market penetration to 2% in 2019, which was disappointing to investors. However, the Company maintained that GOCOVRI would penetrate 25% to 30% of the market and assured that "market access and distribution are solid." On this news, Adamas' stock fell $5.08 per share, or 29.94%, to close at $11.89 per share on November 2, 2018, damaging investors.

18. Then on March 4, 2019, Adamas backed off its prior projection of reaching 2% market penetration in 2019 and refused to provide further guidance. The Company claimed this was due to the slow rate of growth seen in the fourth quarter of 2018 and because it had expanded the free trial program from two weeks to four weeks to allow more physicians to try GOCOVRI. The expansion of the free trial period indicated not only that the Company's failure to differentiate GOCOVRI had resulted in weak demand, but also, partially revealed that the two-week trial period was not enough time for payers to make their reimbursement decision. On this news, Adamas' stock fell $3.99 per share, or 32.84%, to close at $8.16 per share on March 5, 2019, damaging investors.

19. After the end of the Class Period, during Adamas' August 8, 2019 earnings call, Adamas' new Chief Commercial Officer Vijay Shreedhar ("Shreedhar") provided further insight into the Company's March 5, 2019 announcement that it was backing off from Adamas' prior projection of 2% market penetration. Specifically, Shreedhar explained that Onboard's operational

issues had been negatively impacting fulfillment and that these operational issues with Onboard were the primary driver of patient drop-offs. In addition, Shreedhar acknowledged that these fulfillment issues were related to obtaining prior authorization required by payers, which had weakened demand for GOCOVRI among patients and physicians.

20. As a result of the Defendants' wrongful acts and omissions, and the significant decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages. Accordingly, Plaintiff seeks to pursue securities fraud claims under Section 10(b) of the Exchange Act against Defendants and under Section 20(a) of the Exchange Act against each of the Individual Defendants.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) & 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

23. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)). Substantial acts in furtherance of the alleged securities law violations, and/or the effects of the violations, occurred in this Judicial District. Many of the acts charged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

24. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities markets.

III. PARTIES

25. Lead Plaintiff Ralph Martinez, as set forth in his previously-filed certification filed with the Court, incorporated by reference herein (Dkt. No. 29-2), purchased Adamas securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

26. Defendant Adamas is incorporated in Delaware with its principal executive offices located at 1900 Powell Street, Suite 1000, Emeryville, California 94608. Adamas' securities trade in an efficient market on the NASDAQ Global Select Market (the "NASDAQ") under the ticker symbol "ADMS."

27. Throughout the Class Period, Adamas, through its officers and directors, published periodic filings with the SEC, and made public statements that, as alleged herein, contained material misrepresentations and omissions that artificially inflated the price of the Company's shares.

28. Defendant Gregory T. Went ("Went"), served as the Chief Executive Officer ("CEO") of Adamas and Chairman of its Board of Directors since the Company's inception in 2000 until he resigned, effective as of September 16, 2019, and transitioned to a strategic advisory role as a consultant with the Company. Previously, Went cofounded Tethys Bioscience, Inc. and served on its Board of Directors from April 2003 through November 2013. Went also served on the Board of Directors of Angelica Therapeutics, Inc. from January 2006 through the present, and on the Board of Parallele Bioscience (Affymetrix) from November 2001 through July 2005. Went cofounded CuraGen Corporation in 1992, where he served as an Executive Vice President and Director until December 1999. Went received his Ph.D. in Chemical Engineering from the University of California, Berkeley in 1990, and a B.S. in Chemical Engineering from Carnegie Mellon University in 1985. Went has authored at least 20 scientific papers and was listed as an inventor on more than 45 patents and patent applications.

29. Throughout the Class Period, Went frequently spoke to investors and analysts on conference calls and investor conferences. Went possessed the power and authority to control the contents of the Company's public filings with the SEC. During the Class Period, Went signed or authorized the signing of and certified the accuracy of Adamas' Annual Reports on Form 10-K for the years 2017 and 2018, and its Quarterly Reports on Form 10-Q for each quarterly period ended June 30, 2017 through September 30, 2018.[2]

30. Defendant Alfred G. Merriweather ("Merriweather") was the Chief Financial Officer

[2] References to Adamas' fiscal years and quarters are referenced herein as "FY" and "1Q," "2Q," "3Q," or "4Q" respectively, and are followed by the corresponding year.

("CFO") of Adamas from June 28, 2017 until his retirement on December 31, 2019. For more than thirty years prior to joining Adamas, Merriweather served as CFO at numerous life sciences and pharmaceutical companies including RainDance Technologies, Inc., Verinata Health Inc., Celera Corporation, Calypso Medical Technologies, Monogram BioSciences, Inc., ACLARA Biosciences Inc., Syphonix Devices Inc., LipoMatrix Inc., and Laserscope. He received his Bachelor's degree in Economics from Cambridge University in 1975.

31. Throughout the Class Period, Merriweather frequently spoke to investors and analysts on conference calls and investor conferences. During the Class Period, Merriweather signed or authorized the signing of and certified the accuracy of Adamas' Annual Reports on Form 10-K for the years 2017 and 2018, and its Quarterly Reports on Form 10-Q for each quarterly period ended June 30, 2017 through September 30, 2018.

32. Defendant Richard A. King ("King") was Chief Operating Officer ("COO") of Adamas from April 27, 2017 until September 15, 2018, and was responsible for leading the Company's commercial organization and its established teams in marketing, market access, manufacturing, and distribution, as well as, overseeing the company's planning and information technology operations. Prior to joining Adamas, King held executive positions at numerous life sciences companies, including The Scripps Research Institute where he was COO. King also served as President and CEO of AcelRx Pharmaceuticals, Inc., President, COO, and General Manager of Tercica Inc., Executive Vice President of Commercial Operation for Kos Pharmaceuticals Inc., and was also employed at Smith Kline Beecham and Lederle Laboratories. King has served on the Boards of AcelRx Pharmaceuticals Inc., Clarus Therapeutics Inc., and Domain Assoc. LLC. He received a Masters in Business Administration from the Manchester Business School and a Bachelor's of Science in chemical engineering from the University of Surrey.

33. During the Class Period until his departure in September 2018, King frequently spoke to investors and analysts on earnings calls and at investor conferences.

34. Defendants Went, Merriweather, and King are collectively referred to hereinafter as the "Individual Defendants." Adamas and the Individual Defendants are collectively referred to as "Defendants".

35. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the content of Adamas' reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements, pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

IV. RELEVANT NON-PARTIES

A. Adamas Executives

36. Rajiv Patni, M.D. ("Patni") joined Adamas as Chief Medical Officer in June 2015 and continued to serve in that position throughout the Class Period. Prior to Adamas, Patni served in a variety of executives roles at several pharmaceutical companies.

37. Vijay Shreedhar ("Shreedhar") became Adamas' Chief Commercial Officer in May 2019. Prior to joining Adamas, Shreedhar served in a variety of sales and marketing roles of increasing responsibility in multiple therapeutic areas at Amgen, a biotechnology company, from August 2005 to May 2019.

38. Melissa Masterson ("Masterson") was Adamas' Senior Vice President of Market Access, Distribution and Commercial Operations throughout the Class Period and reported directly to Went. She departed the Company in August 2019. Prior to joining Adamas, Masterson served in a variety of market access roles of increasing responsibility at Otsuka America Pharmaceutical, Inc., Strativa Pharmaceuticals, and Forest Pharmaceuticals.

39. Dean Hart ("Hart") was Adamas' Senior Vice President of Sales from January 2018 through August 2019. Hart has been the President of CommEx Consulting since April 2017, which specializes in sales force execution, launch excellence, and leadership development.

40. Rajesh Pahwa ("Pahwa") was the Lead Investigator for the GOCOVRI clinical studies and Chief of the Parkinson's and Movement Disorder Disease Division at the University of Kansas Medical Center. He has been a Professor of Neurology at the University of Kansas Medical Center since July 1991.

B. Adamas Former Employees

41. Former Employee 1 ("FE1") was employed by Adamas as the Mid-Atlantic Regional Business Director from September 2017 until approximately July 2019. The Mid-Atlantic Region covered North Carolina, Virginia, Washington D.C., Maryland, part of Delaware, Pennsylvania (excluding Philadelphia), Ohio, and parts of Kentucky and West Virginia. FE1 was hired to help launch GOCOVRI. FE1 and five other Regional Business Directors were responsible for recruiting 59 sales representatives, who started in November 2017 and were trained in Dallas, TX the first week of December 2017. Ten sales representatives reported to FE1. FE1 and the other Regional Business Directors reported to Hart, who reported to King, and after King's departure, reported directly to Went.

42. FE2 was employed by Adamas as a Senior Medical Science Liaison ("MSL") from April 2018 until December 2018 and was responsible for a territory that included Texas, Arkansas, and Louisiana. The MSLs reported to a Manager of Medical Affairs, who reported to Patni, who FE2 believed reported to Went. MSLs typically hold more advanced degrees, such as an M.D., Ph.D., Pharm.D. or nursing degree, and were supposed to have more knowledge of GOCOVRI data and be able to discuss it in more depth. MSLs were field-based and answered doctors' questions and collected doctors' feedback about GOCOVRI.

43. FE3 was an Adamas Neurology Account Specialist from November 2017 until August 2018. FE3 had worked in pharmaceutical sales for 20 years and specialized in neurology drugs for 12 of those years. FE3 was responsible for the sale of GOCOVRI in the Greensboro and coastal region of North Carolina and reported to a Regional Manager, who reported to Hart, who

reported to King.

44. FE4 was the VP of Marketing at Adamas from June 2017 through February 2019 and reported to King, and then, after King's departure, reported directly to Went. FE4 was responsible for the commercial aspect of the GOCOVRI launch, including sales materials and print ads, and also served as the Project Leader for the GOCOVRI brand. FE4 said this was a cross-functional team consisting of other department heads including Market Access, Sales, and Clinical who all reported to King. As part of FE4's responsibility as the Project Leader for the brand, all the manufacturing and purchase orders associated with GOCOVRI came through FE4 and this team.

45. FE5 was an Adamas Neurology Account Specialist from November 2017 through January 2020, who initially reported to Regional Business Director Dan Wilson, and later reported to Steve Welsh. Wilson and Welsh both reported to Hart, who reported to King, and subsequently reported to Went after King's departure. FE5 was responsible for selling GOCOVRI in San Antonio and south Texas and was appointed to a Sales Advisory Board for the first year of FE5's employment, which consisted of seven or eight sales representatives, one from each region, as well as Hart. The purpose of this Board was to provide feedback about the sales process and any issues encountered with selling GOCOVRI. FE5 explained that the Sales Advisory Board met at least once every quarter in the year GOCOVRI was launched, and were led by Hart via conference call, apart from one in-person meeting in the summer of 2018 at the Company's California headquarters and which Went attended. FE5 said occasionally people from marketing or compliance might attend the Sales Advisory Bard meetings and would take what was discussed back to work on improvements.

46. FE6 was a Senior Director of Business Analytics at Adamas from October/November 2016 until November 2018. FE6 was responsible for market research for all compounds in the Adamas portfolio. From the time FE6 began at Adamas until approximately November 2017, approximately 80% of FE6's time was spent on GOCOVRI market research and 20% on other compounds in development. FE6 said this role involved developing the revenue forecasts for GOCOVRI, which were initially derived from market research, but once a product was launched, actual sales trends are factored into forecasts. FE6 explained that market research entailed

determining the assumptions used to forecast GOCOVRI's potential market size, and involved talking to doctors and patients to determine their interest level, the number of potential patients, the type of insurance for those patients, all of which helped determine the market size for GOCOVRI.

47. In or around November 2017, FE6 was no longer responsible for GOCOVRI's forecasting, but still performed market research for GOCOVRI and other compounds the Company was interested in developing. For the last six to twelve months of FE6's employment at Adamas, approximately 50% of FE6's time was spent on market research for GOCOVRI and 50% on market research for other compounds. FE6 reported directly to Went until April 2017, when King was hired, and reported to King until King was terminated in September 2018. After King departed, FE6 did not report to anyone, although FE6 explained that there was a dotted line to Masterson.

V. BACKGROUND

A. Background Of Adamas, GOCOVRI, And Dyskinesia

48. Adamas is a pharmaceutical company that was founded by Went in 2000 and specializes in developing drug treatment therapies for chronic neurological disorders. Adamas did not create novel new compounds, but rather added a timing feature to existing compounds.

49. GOCOVRI, formerly referred to as ADS-5102, is the first treatment that Adamas developed and marketed on its own. GOCOVRI is an extended-release formulation of amantadine for the treatment of levodopa-induced dyskinesia ("LID"). Levodopa therapy replaces the lost dopamine in patients with Parkinson's disease (sometimes referred to as "PD"), allowing patients improved control over their bodily movements. The primary side effect associated with levodopa treatment is dyskinesia, the involuntary and uncontrolled movements that occur when there is too much dopamine.

50. Amantadine IR is an inexpensive generic drug that had been used to treat dyskinesia for decades. It was "indicated in the treatment of parkinsonism and drug-induced extrapyramidal reactions," which are "commonly referred to as drug-induced movement disorders," such as dyskinesia. For many patients with LID, amantadine IR may not be effective or tolerable, causing these patients to discontinue using the drug.

51. Given these issues with amantadine IR for many patients with LID, prior to

GOCOVRI's approval, the primary treatment method for dyskinesia was to adjust the dose and timing of levodopa to minimize dyskinesia and "OFF time." OFF time refers to periods of rigidity and stiffness which occur when there is too little dopamine. Amantadine IR was also used in more severely dyskinetic patients, often in conjunction with dosing adjustments.

52. GOCOVRI is to be administered orally once daily at bedtime. Its extended-release formulation resulted in patients experiencing high concentrations of amantadine in the morning and maintained throughout waking hours, when dyskinesia and OFF time were most bothersome, and meant that patients would not have to adjust their levodopa dose downward, thus decreasing OFF time. In addition, GOCOVRI promised to "moderate the sleep-related adverse events" that were associated with amantadine IR because its formulation and administration resulted in it being at its lowest concentration at night.

53. Went acknowledged on a May 9, 2017 earnings call that for patients taking amantadine IR, "it's not durable and they don't stay on it for very long." Defendants thus understood that GOCOVRI's commercial success depended on their ability to demonstrate that GOCOVRI was more effective and tolerable than amantadine IR.

54. On August 24, 2017, the FDA approved GOCOVRI. The drug was made available to patients shortly thereafter in October 2017, but the Company did not fully commercially launch GOCOVRI until January 2018.

55. Successfully commercializing GOCOVRI was crucial to Adamas' success. Before GOCOVRI became commercially available in October 2017, Adamas had earned just $3,000 total for the first three quarters of 2017, generated from collaboration and license agreements with other companies. Adamas acknowledged in its 2017, 2018, and 2019 Form 10-K's that "[o]ur success depends heavily on successful commercialization of GOCOVRI…. To the extent GOCOVRI is not commercially successful, our business, financial condition and results of operations will be materially harmed." GOCOVRI was the primary source of revenue for the Company both during and after the Class Period, representing 99% of Adamas' revenue in 2017, 2018, and 2019, as indicated in Adamas' Form 10-K for the year ending December 31, 2019, filed on February 25, 2020.

B. Payer Coverage Was Critical To GOCOVRI's Success

56. During the Class Period, GOCOVRI's list price was $28,500 per year, or $2,375 per month. This high cost meant that payer coverage was necessary. Payers for prescription drugs include governmental payers, such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Payers generally seek to minimize their spending on pharmaceuticals in order to lower overall healthcare costs. The primary tool payers use to contain pharmaceutical costs is formulary placement. A payer's formulary is the list of all pharmaceuticals for which the payer will provide coverage. The formulary will also provide patient co-pay amounts depending on the tier the pharmaceutical is placed on. For instance, a generic drug might have a $5 co-pay while a newer brand name drug might have a $50 co-pay. While a payer may provide some reimbursement, high co-pays may cause patients to not fill prescriptions or to drop treatment.

57. Adamas acknowledged in each of its annual reports filed on Form 10-K's for the years ending December 31, 2016 through December 31, 2018 that "[c]overage, reimbursements, and placement decisions for a new product are based on many factors including the coverage, reimbursement, and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, and the clinical need for the new product." Adamas was aware that generic amantadine IR was approved for a similar indication and placed on preferred or top tiers on most formularies, and thus would play an integral role in payers' coverage decisions.[3]

58. Payers also use other pharmaceutical cost containment strategies, such as medical necessity, prior authorization, and step-through requirements, which are frequently coupled together. Medical necessity refers to a decision by a payer that a drug is necessary to treat a diagnosed medical problem. Most payers will not provide reimbursement for drugs that they deem to be not medically necessary. Prior authorization means that the payer will not cover the cost of

[3] For example, Adamas' 2016 10-K, filed on February 28, 2017, stated that "most payers are likely to extend coverage to [GOCOVRI] and that its placement on payer formularies and the amount of reimbursement will be influenced by the aforementioned products, generic amantadine, and generic and branded treatments for symptoms of Parkinson's disease."

the drug until a patient's doctor has obtained approval from the payer, which may include the doctor or prescriber contacting the payer and describing the specific set of conditions that makes the drug therapeutically appropriate. Step-throughs involve a payer requirement that a patient try a cheaper therapeutic alternative prior to approving a more expensive drug. Step-throughs may also involve a showing that the cheaper alternative was not effective or well tolerated. Step-throughs may be required to prove medical necessity or to gain prior authorization, or may be an independent requirement. Meeting these requirements necessarily involves patients and physicians providing payers with various forms of documentation to inform the payers' decision.

59. Coverage for GOCOVRI thus depended on payers differentiating GOCOVRI from generic amantadine IR, such that they would appreciate the value proposition of GOCOVRI to justify its high cost. However, Adamas did not perform a study comparing the efficacy and tolerability of GOCOVRI to amantadine IR (as detailed further in ¶¶69-71, *infra*), which posed a significant hurdle in differentiating the two drug treatments. Unsuccessful differentiation of GOCOVRI to amantadine IR put Adamas at risk that payers would: (i) not reimburse the drastically higher priced GOCOVRI; (ii) place it on a disadvantaged formulary tier with lower levels and/or amounts of reimbursement; (iii) require a showing of medical necessity and/or a prior authorization; and/or (iv) require that patients first step-through amantadine IR before providing reimbursement.

60. Payers' requirements to obtain reimbursement impact demand for GOCOVRI due to the time and burden of providing documentation and waiting for fulfillment, and require patients and physicians to appreciate the benefits of GOCOVRI compared to amantadine IR in order to undertake the burdensome payer requirements. Step-through requirements were a particularly onerous obstacle, and, during the Class Period, analysts covering Adamas were greatly interested if payers were requiring a step-through—the lack of a step-through requirement was indicative of payer support.

C. Efficient Distribution Was Critical To GOCOVRI's Success

61. Prior to GOCOVRI's commercial launch, Adamas chose to distribute GOCOVRI through a specialty pharmacy, AllianceRx Walgreen's Prime, which also provided reimbursement support through a program called GOCOVRI Onboard ("Onboard"). Masterson described Onboard

at the September 18, 2017 Investor & Analyst Meeting, stating, "GOCOVRI Onboard will do the benefit verification. They will provide any [prior authorization] or reimbursement support that's required to get patient on to medication."

62. On the November 2, 2017 earnings call, King provided further details about Onboard, stating, "the interaction is singular and uniform for both patients and physicians as well as for payers, by the way, and in terms of the management of reimbursement support for patients." King noted, "we've designed it to be a single point of interaction, rather than potentially multiple points of interaction for the patient." King also described the "treatment form" which was used "in lieu of a prescription to establish the ability for GOCOVRI Onboard to support patient reimbursement." King said, "we've taken a lot of input there from physicians to make sure that, that is a simple-to-use-form." King concluded, "we've designed this patient interaction, this patient assistance program well to meet the needs of both physicians and patients."

63. Adamas thus heavily relied on the specialty pharmacy operating smoothly and efficiently for GOCOVRI's commercial success. The choice to distribute through a specialty pharmacy meant patients and physicians could not fill prescriptions at retail pharmacies, requiring them to familiarize themselves with the separate processes of Onboard. Onboard was responsible for obtaining from patients and physicians any payer-required documentation to establish prior authorization, medical necessity, and step-through requirements. As such, the operational acumen of Onboard was critical to GOCOVRI's success.

64. Adamas also did not to provide physicians with free samples of GOCOVRI—a decision the Company reversed well after GOCOVRI's commercial launch in or around March 2019 (as detailed further in Sec. VI.D.4, *infra*). Instead, a two-week supply of GOCOVRI was offered to patients while waiting for payers to approve reimbursement. This program was called "QuickStart" and was administered by Onboard. At the September 18, 2017 Investor & Analyst Meeting, King announced "we won't sample this program into the physician's office….[B]ecause we're going to provide access from QuickStart to all patients, that will be the support mechanism that we'll use to help patients as they work their way through the reimbursement challenges that will be integral for any part of this being introduced. So we'll replace sampling with that…" Masterson explained

during this same meeting that QuickStart "will be triggered on day 5 to help patients get onto medication as quickly as possible as GOCOVRI Onboard works through any type of prior authorizations or any barriers that may be in place." FE4 explained that QuickStart was limited to 14 days because of cost concerns and that it would cost Adamas much more to provide free product for 28 days.

65. The decision to replace free samples to physicians with QuickStart increased the Company's reliance on GOCOVRI's clinical data, because physicians could not evaluate GOCOVRI's efficacy or tolerability without writing prescriptions. In addition, providing only a two-week supply increased the Company's reliance on payers' support and Onboard's operational efficiency, such that the reimbursement process and addressing any payer requirements would not take longer than two weeks.

VI. SUMMARY OF THE FRAUD

A. Prior to the Commercial Launch, Adamas Touted Payer & Physician Support For GOCOVRI

66. Prior to the start of the Class Period, on Adamas' May 9, 2017 earnings call, Went stated that "our research… indicated that payers appreciate the strong value proposition of ADS-5102." Went assured investors and analysts that "the data that we present for ADS-5102 has been very well-received" by payers and stated that "this product will be viewed on the merits of this data. It will be viewed as differentiated…." Went further indicated that payers were unlikely to require a step-through, stating, "we have not been at this point receiving significant pushback with regards to that given the size of the population or with regard to IR amantadine likely because of its relatively light use in this population[,]" and quantified the size of the population of patients using amantadine IR: "we estimate from the work we've done approximately 7% of patients are taking amantadine. The problem is when they do, it's not durable and they don't stay on it for very long."

67. On the August 8, 2017 earnings conference call (the "August 2017 Call"), during his prepared comments updating investors and analysts on Adamas' commercialization plans, King explained that "[i]n terms of market access, we have begun to reach out to payers to introduce them to Adamas and to raise awareness to the anticipated approval of ADS-5102." King further stated

that "we are in the final stages of validating our commercial communications. And are very pleased that they appear to resonate with prescribers, payers and people with Parkinson's disease." King further noted that "we are very pleased with the reception we're getting from payers…." During the question-and-answer portion of this August 2017 Call, in response to a question about how quickly Adamas would be able to penetrate the commercial payer and Medicare segments, King responded that "the value of deferring the launch date until January 1 of 2018 is that we get effectively 4 months to go and interact with payers."

68. Also on the August 2017 Call, King assured analysts in response to their questions that GOCOVRI pricing would be "consistent with the value proposition for patients. And we believe we've got a strong value proposition, given the differentiated clinical nature of ADS-5102." King further emphasized that physicians and payers were differentiating GOCOVRI from amantadine IR, and claimed there was no anticipation of a step-through requirement:

> KING: …We've obviously done a fair amount of assessment of ADS5102 with physicians and with payers. The profile for the product, as I mentioned in the comments, resonates extremely well. And they don't see this profile as really having much to do with the amantadine IR profile, that they - - that's currently on the marketplace. They recognize that amantadine IR is not approved for this indication. And that if ADS-5102 is approved for this indication, and with the clinical data set that is available to support it, that there is no anticipation of requiring a step-through of amantadine IR to get to 5102.

69. King's statements were contrary to the opinion of Dr. Aparna Shukla, a professor of movement disorders, department of neurology and director of clinical trials at the University of Florida, as expressed in her editorial entitled "Extended-Release Amantadine – A Smart Pill for Treatment of Levodopa-Induced Dyskinesia but Does the Evidence Justify the Cost?" published in the August 2017 volume of the Journal of the American Medical Association ("JAMA"), a leading peer-reviewed medical journal.[4] Dr. Shukla's editorial analyzed the results of the ADS-5102 Extended Release Capsules for the Treatment of Levodopa Induced Dyskinesia (EASE LID) Study (as part of Adamas' Phase 3 clinical study evaluating the efficacy and safety of GOCOVRI).

[4] *Available at* https://jamanetwork.com/journals/jamaneurology/article-abstract/2630678 (last accessed May 13, 2020).

70. In her JAMA editorial, Dr. Shukla wrote:

> There are several important limitations of the study. There was no active comparison with immediate-release amantadine. There was an early and unexpected termination of the study. The study did not shed light on responders to amantadine therapy vs nonresponders. There was also an underrepresentation in the sample of patients with young-onset PD who in general tend to have more severe LID (the mean age at onset for PD in the study was about 56 year).

71. Dr. Shukla concluded that "until a true comparison with a generic Amantadine IR pill is performed, it remains unclear whether the potential benefits [of GOCOVRI] justify the costs." In her editorial, Dr. Shukla also described amantadine IR as a "robust" and "powerful" treatment for dyskinesia, noting that it was "found to reduce the severity of peak-dose dyskinesia and to reduce the overall duration of troublesome LID." Dr. Shukla's editorial put Adamas and the Individual Defendants on notice that the Company's reliance on its published clinical data to drive demand would be lacking for many decision makers—and that payers' coverage decisions were even more critical in order to address cost concerns physicians would have without a true differentiation of GOCOVRI to amantadine IR.

72. Moreover, FE6 explained that during the first half of 2017, Adamas did a quantitative study of physicians to gauge the demand and potential market size for GOCOVRI. Contrary to King's August 8, 2017 claim that "they don't see this profile as really having much to do with the amantadine IR profile," FE6 said some physicians, as part of Adamas' quantitative physician study, commented that GOCOVRI sounded just like amantadine, and that, moreover, Adamas anticipated this confusion because GOCOVRI was in fact a reformulated version of amantadine. FE6 said this early market research showed that there was a segment of doctors unlikely and unwilling to switch to GOCOVRI. FE6 explained that some doctors that partook in Adamas' 2017 physician study, were already dosing generic amantadine like GOCOVRI to get the same result and thus indicated they were unlikely to switch to GOCOVRI. FE6 said the Company knew going into the quantitative physician study that there would be physicians unwilling to try GOCOVRI because they viewed it as a reformulated version of amantadine.

73. In the first half of 2017, FE6 worked with an outside consultant in an effort to forecast demand for GOCOVRI and to project what percentage of the market GOCOVRI would capture.

FE6 said that these results were presented to Went, who then had the consultant fired because Went felt the projections were too low and did not like how the numbers were presented. FE6 said another consultant was thereafter hired in the first half of 2017 who came up with the same projections, Went was again disappointed with the projections. FE6 explained that unlike sales and marketing which tend to present a "rosy" viewpoint, the role of market research was to bring in objective facts in defining the market and projected demand for a specific product, like GOCOVRI. FE6 described Went was a narcissist and said that Went frequently did not accept information provided to him by FE6.

74. FE4 detailed Adamas' assessment of GOCOVRI with payers prior to launch. Contrary to King's August 8, 2017 statement that "there is no anticipation of requiring a step-through of amantadine IR to get to 5102", FE4 stated that Adamas always anticipated that some payers would require a step-through of amantadine and step therapy was accounted for in the Company's forecasts. When FE4 began working for Adamas in June 2017, FE4 was informed that Adamas hired an outside market research company to survey payers to understand whether and how GOCOVRI would be covered at different price points. FE4 said the survey detailed the product profile to payers, including that GOCOVRI was an extended release version of amantadine IR. FE4 said in or around July 2017, a summary of the results of this survey was circulated to all commercial personnel and that King and Went received it. Moreover, FE4 stated that in or around July 2017, the company that performed the payer survey presented the results at a meeting attended by FE4, Went, and King. FE4 said that the fact that GOCOVRI was a reformulation of the generic drug amantadine IR drove down the payer support for pricing. FE4 said the survey results showed payers favored the lowest price range; and that regardless of the potential price points for GOCOVRI that were presented to payers as part of the survey, certain payers indicated that they would impose the same types of access restrictions, including a step through of amantadine. FE6 similarly recalled a pricing survey conducted by a third-party prior to launch to determine whether GOCOVRI would be on the payers' formulary, which found that payers would require prior authorization to access GOCOVRI, and some payers would require step therapy.

75. FE2 further explained that managed care companies frequently require step therapy

when there is a big price difference between two drugs without a big enough difference in efficacy, a fact Adamas acknowledged in its 2016-2018 Form 10-Ks and stated that payers' decisions are based in part on "the availability of generics available [to treat] similar indications." Given the drastic price difference between GOCOVRI and amantadine IR and the lack of clinical data showing superior efficacy, Defendants certainly anticipated, or were deliberately reckless in not anticipating, that some payers would require step therapy. Indeed, Went later admitted on the Company's November 1, 2018 earnings call when asked if OSMOLEX's approval would impact GOCOVRI's coverage, that some plans were requiring patients to first try amantadine and that had been the "market reality… before we launched the product[:]"

> WENT: And so I think [OSMOLEX] will be largely independent from us, in terms of how it ends up being reimbursed and what its challenges will be, and whether or not it gets folded into something that physicians are encouraged to try, as some plans have done with amantadine IR, I think remains to be seen. But again, we are -- we've been facing that market reality since, well before we launched the product, and are pleased with how that is playing out right now, in terms of any kind of a prior attestation of use of amantadine IR.

76. Shortly after GOCOVRI was approved on August 24, 2017, Adamas hosted an Investor & Analyst Meeting on September 18, 2017 (the "September 2017 Meeting"), and which was attended by King, Went, and Merriweather, along with Masterson, Pahwa, and Patni. During this meeting, King detailed the Company's "extensive research" of payers, which included "talk[ing] to 5 pharmacy benefit managers, 8 national-scale managed care organizations, 12 more regional managed care organization covering 125 million lives in the U.S." King further stated:

> We also presented to payers the fact that amantadine IR, which they know has been available in Parkinson's disease for some time, doesn't necessarily do a great job in providing support for these patients… [H]aving presented those background elements to payers, what we concluded and what the payers were willing to support us at was the GOCOVRI list price at $28,500 per year or $2,375 per month…

77. King's statement failed to disclose that Adamas' July 2017 market survey of payers revealed that, even in that lowest pricing tier, payers indicated they would require prior authorizations, and certain payers would require step-therapy.

78. Masterson also discussed market access at the September 2017 Meeting, stating, "[t]hrough our market research and discussions that we've had to date with payers, we anticipate

there will be broad coverage for GOCOVRI, given its novel indication and established clinical benefit for patients." Masterson noted that "about 20 payers cover about 85% of the lives in the United States" and assured "[w]e've already started discussion. We've already actually done a clinical presentation with one of the largest in the space."

79. During the September 2017 Meeting, Masterson also explained the reimbursement paradigm GOCOVRI faced when it entered the market:

> Some of the largest commercial payers now like UnitedHealthcare, like CVS/caremark, like Express Scripts also do not cover a product until they have an opportunity to review it. Most of the commercial plans will be reviewing the product within 6 months of launch. Similar to Medicare, commercial[] [is] the same type of dynamic. While they're going through the review, you can get coverage through a provisional process, typically known as medical necessity, where paperwork is filled out, it goes to the payer. When medical necessity is approved, a patient is approved for a 12 month period of time to be able to get medication.
>
> And then, also in the commercial space, we anticipate there will be some plans that will automatically cover us at a Tier 3 or that nonpreferred tier until they review the product. Some of those plans until they formally review the product may have prior authorizations in place to assure appropriate use. Appropriate use prior authorizations are typically as it relates to the diagnoses and also ensuring quantities aligned with the package insert.

80. Adamas and the Individual Defendants thus understood, at the latest by September 18, 2017, that proving medical necessity, securing a prior authorization, or requiring a step-through of amantadine would be required by payers prior to providing patient reimbursement for GOCOVRI.

81. The Lead Investigator for the GOCOVRI clinical studies and Chief of the Parkinson's and Movement Disorder Disease Division at the University of Kansas Medical Center, Rajesh Pahwa ("Pahwa") also presented at the September 2017 Meeting. Pahwa commented that there was a perception of amantadine IR that "after a few months, it loses its efficacy." Pahwa stated "one question I'm often asked [about GOCOVRI] is… What is the difference?" Pahwa explained that the side effects from GOCOVRI "you also see with amantadine IR." Reflecting the concerns expressed by Dr. Shukla, Pahwa discussed the lack of data directly comparing GOCOVRI to amantadine IR and the issues with the open label study comparing the two stating, "if you were a tech reporter, you would blow this [open] study apart. But the thing is, that's the best data we have

on talking about IR and GOCOVRI. Yes, this is an open-label study. Yes, this could be a biased group."

82. Nevertheless, at this same September 2017 Meeting, King described GOCOVRI as having "preference brand share" and indicated that Adamas believed GOCOVRI's market share would "ultimately [be] in the 25% to 30% range," and that it would obtain "a little under 1% penetration" in the first year. King further claimed that 59 sales representatives would be able to "target 94% of the physicians who deal with the majority of these patients with Parkinson's disease…." Merriweather assured "we're also very comfortable… because of the clinical differentiation of the product getting up into that 25% to 30% at peak concentration of our target population."

83. On November 2, 2017, Adamas held earnings call (the "November 2017 Call") at which Went, Merriweather, King and other Adamas executives were in attendance. During this November call, Patni noted that "[s]ince the [FDA] approval on August 24, 2017], we have received numerous questions about GOCOVRI and about how it is differentiated from existing treatment strategies for dyskinesia, including the use of amantadine immediate release. Some have commented that GOCOVRI is simply a long-acting amantadine." But Patni went on to explain how GOCOVRI was different, stating that "GOCOVRI was designed to achieve high sustained concentrations of amantadine from awakening and throughout the day, when dyskinesia symptoms frequently occur."

84. An analyst followed up on Patni's remarks during the November 2017 Call, and asked if the Company's marketing materials would make it clear that "GOCOVRI is not an extended release amantadine," to which King responded that "physician experience of amantadine IR is in general that it lack the designed efficacy," and noting GOCOVRI's efficacy data, further stating he was "comfortable and confident that, that's enough of a clinical comparison that we can substantiate in the minds of physicians."

85. Also on the November 2017 Call, King reported on the Company's progress with payers:

> We have also begun outreach to payers and have scheduled clinical presentations with 7 out of the top 10 payers in the country for later this year. The payers are particularly interested in GOCOVRI as a first in indication medicine for dyskinesia

patients, who they recognize are in need. We anticipate broad payer coverage for GOCOVRI that will grow over the course of 2018.

B. Following Commencement Of GOCOVRI's Full Commercial Launch, Defendants Falsely Claimed No Payers Were Requiring Step Therapy

86. GOCOVRI officially fully launched in January 2018. On January 22, 2018, Adamas filed a Form 8-K announcing updated risk factors, which, in part, stated that "although no payer has done so to date, a payer may determine to require patients to use immediate release amantadine for dyskinesia (even though it is not approved for that indication) prior to receiving reimbursement for GOCOVRI." This statement was repeated in the Company's FY 2017 annual report filed with the SEC on Form 10-K on February 22, 2018, as well as its 1Q 2018 quarterly report filed with the SEC on Form 10-Q on May 3, 2018. However, contrary to these statements, several payers were already requiring a patient to use amantadine prior to receiving reimbursement for GOCOVRI, as indicated in the following chart:

Payer	Decision Date	Reimbursement Requirements[5]
Centene	10/10/2017	Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced On 4/12/18 following requirement was added: Medical justification supports inability to continue use of immediate-release amantadine (e.g., contraindications to excipients)
Tricare	11/16/2017	The Department of Defense Pharmacy and Therapeutics Committee minutes from November 15-16, 2017 indicate that GOCOVRI required both medical necessity (MN) and prior authorization (PA), which involved: Medical Necessity (MN) criteria: The patient has experienced significant adverse effects to the formulary alternative amantadine IR that are not expected to occur with Gocovri. Manual PA Criteria—Gocovri is approved if: • The patient is ≥18 years old AND • Has a diagnosis of Parkinson's Disease AND • Has had therapeutic failure of a trial of amantadine 200 mg immediate release tablets administered twice daily
Idaho Medicaid	11/17/2017	The formulary lists GOCOVRI as a non-preferred drug. Non-preferred drugs require failure of 1, 2 or 3 preferred agents for prior authorization approval. Among the list of preferred drugs was amantadine capsules, syrup.

[5] This list is intended to be illustrative, not exhaustive, as many formularies that were in place at the time are no longer publicly available or have since been revised without indicating when revisions were made. The payers' decisions, or the relevant excerpts of the formulary, are attached hereto as Exhibits A-H.

Payer	Decision Date	Reimbursement Requirements[5]
Blue Cross Blue Shield Federal Employees Program	12/8/2017	There was a requirement to show GOCOVRI was medically necessary which required among items that: Prescribing physician has attempted to adjust levodopa therapy to decrease dyskinesia AND Inadequate treatment response or intolerance to short acting amantadine
Delaware Medicaid	1/24/2018	Gocovri is listed as a Non-preferred agent for which prior authorization is required. The criterion says: Two preferred products required before a non-preferred product will be approved. Among the preferred agents are amantadine capsules, solution.
Prime Therapeutics/ Blue Cross Blue Shield of Alabama	Jan 2018	GOCOVRI required prior authorization. The approval criteria included a requirement that: The patient's medication history indicates the use of immediate release amantadine OR The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immediate release amantadine
Kaiser Permanente	March 2018	Non-formulary amantadine ER (GocovriTM) will be covered on the prescription drug benefit when the following criteria are met: * Pt has dyskinetic movements that have responded to adequate trial (≥4 week) of amantadine IR -AND- * Pt has failed amantadine IR due to frequency of dosing
Vermont Medicaid	4/27/18	[P]atient has a documented side effect, allergy, or treatment failure with immediate release amantadine. Note: treatment failure is defined by a decrease in effectiveness despite attempts to increase dosage to 300mg/day or by temporarily discontinuing amantadine for several weeks and restarting therapy.

87. Many of these payers were among the largest in the United States. Centene insures over 14.7 million people among all of its affiliates. Tricare, a health insurer for the Department of Defense, covers approximately 9.4 million people. Blue Cross Blue Shield Federal Employee Program provides benefits to approximately 5.3 million people. Prime Therapeutics is aligned with BlueCross Blue Shield networks and covers over 28 million individuals in the U.S. Kaiser Permanente, a large west coast health insurer, covers approximately 12 million people. These decisions were in most cases publicly available on the payers' websites, and based on information and belief, were reported to Defendants by the payers when made.

88. Defendants would have also been made aware of step therapy requirements because Onboard's prescription fulfillment data was available on Tableau dashboards.[6] FE4 said commercial analysts and all executives at the level of Vice President and above, including the Individual Defendants, had access to the dashboards and received monthly fulfillment reports from Onboard. FE3 and FE4 said the dashboards provided real time fulfillment data from the time the prescription form was sent to Onboard, including among other items the rate of fulfillment, the time to fulfill, and the status or reasons the prescription was not fulfilled or not yet fulfilled. Within a few months after launch, FE3 received access to the dashboards that provided Onboard's data regarding fulfillment and reimbursement. FE6 similarly recalled Onboard's fulfillment data being available on the Tableau dashboards, including the time to fulfill and reasons why prescriptions were not fulfilled, excluding any information that might have violated HIPAA.[7]

89. FE4 knew King and Went were familiar with the fulfillment data because FE4 regularly discussed it with them and Went was very involved. Furthermore, FE4 noted that Adamas was a small company,[8] and thus FE4 would be surprised if Merriweather was not familiar with the data. FE6 claimed the whole benefit of distributing GOCOVRI through the specialty pharmacy was its ability to track this fulfillment data, and recalled Went and King oftentimes discussing fulfillment issues. FE3 recalled that half of prescriptions were held up because managed care was not willing to reimburse unless the patient had previously used generic amantadine, and these issues were reported to sales managers. Thus, the Individual Defendants would have known, or were deliberately reckless in not knowing, that payers were requiring step-therapy, prior authorization,

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[6] Tableau Software ("Tableau") is an interactive data visualization software company focused on business intelligence. A Tableau dashboard allows non-technical users to access and use data with creative and real-time visualization and is a collection of several views that allow users to compare a variety of data simultaneously.

[7] The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

[8] In its 10-Ks for the FY 2016-2018, Adamas respectively reported that it had 69 full-time equivalent employees as of December 31, 2016, 147 full-time equivalent employees as of December 31, 2017, and 159 full-time equivalent employees as of December 31, 2018.

and/or medical necessity through the availability of, and the Individual Defendants' access to, the Onboard fulfillment data.

90. Defendants would have also been aware of these payer decisions requiring patients to step-through amantadine because, as Masterson stated on the September 2017 Meeting, Adamas was regularly meeting with the top payers who covered 85% of the U.S. population. FE4 said that the Company had an Excel spreadsheet used for forecasting which was broken down by payer, their expected fulfillment rate, and the expected number of patients per payer. Defendants also indicated that they were tracking coverage decisions, including step therapy requirements, by regularly reporting on their meetings with payers and coverage expectations. FE4 similarly indicated that actual fulfillment was compared to the forecasts.

91. In addition, Defendants would have known step therapy requirements through the Sales Advisory Board, which according to FE5 was created for the express purpose of providing executives feedback about sales and market access issues. Furthermore, GOCOVRI was essentially Adamas' first and only product. Payers' coverage decisions, particularly those involving step therapy, were critical to the success of GOCOVRI and thus Adamas, and Defendants knew or were reckless in not knowing that payers were requiring step therapy.

C. Defendants Continued To Tout That GOCOVRI Was Sufficiently Differentiated And That Reimbursement Was Happening Throughout The Remainder Of The Class Period

1. FDA Approves Osmolex Adding A New Competitive Threat

92. On February 20, 2018, the FDA approved OSMOLEX ER ("OSMOLEX"), another extended-release version of amantadine, for the same indication as amantadine IR. OSMOLEX was seen as a potential competitor to GOCOVRI. William Blair issued a report the same day as OSMOLEX's approval, titled "Osmolex ER FDA Approval Places Indirect Competitive Pressure on the Gocovri Franchise." The report stated that Adamas shares were "down about 20%" and

noted, "Gocovri ER was left off Express Scripts' preferred formulary list while generic amantadine IR remained —this highlights ongoing pricing and reimbursement pressures."[9]

93. On Adamas' February 22, 2018 earnings call (the "February 2018 Call"), King and Went sought to assure investors that payers and physicians had differentiated GOCOVRI from amantadine IR, and because Osmolex was equivalent to amantadine IR, its approval would not impact GOCOVRI's prospects. King stated on the February 2018 Call that, "if you believe that OSMOLEX ER is basically an equivalency to IR amantadine, then I don't think that value proposition to either the payer or to the physician community changes in that light." Went similarly stated, "all of our attempts to look at indications for GOCOVRI are in light of the [] availability of immediate-release amantadine as potential treatment… And so I really don't see it affecting it at this instance."

94. King went on to assure investors that the value proposition derived from GOCOVRI's efficacy and safety profile was resonating with physicians and payers:

> [F]or about the last 4 or 5 months right now, we've been presenting to the payer community and the physician community, the value proposition that's derived from that dataset. And that's in the environment in which amantadine IR is available. And that's been resulting in very strong, resonant support for GOCOVRI at both the physician and the payer level.

95. An investment firm, Cowen, published a report on February 22, 2018 stating, "if reimbursement is a bit more mixed than management is indicating – and Osmotica's Osmolex ER [] launches at a significant discount (which we believe is likely) – then the managed care/formulary situation could become a bit more complicated." The report concluded, "with seemingly only one way to gain access (i.e. managed care/pricing) – this does need to be monitored and we are sensitive to it."

[9] An earlier report issued on February 4, 2018, by the investment bank advisory firm, Evercore, similarly noted that GOCOVRI was excluded from Express Scripts 2018 formulary, impacting "11% of total commercial lives" in the United States.

2. Defendants Continue To Publicly State That Payers Were Not Requiring Step Therapy

96. On April 19, 2018, Piper Jaffray issued a report detailing insights it gathered into the payer landscape from senior management meetings with investors:

> ADMS did make it clear that they are not seeing any "hard" step-edits. In other words, payers are not requiring a patient to prospectively try a course with immediate-release (IR) amantadine before allowing access to Gocovri. The main step edit in place is one where the physician has to attest that the patient has been on a previous course of IR amantadine. To be clear, a sizable portion of PD patients (particularly more advanced PD patients managed by movement disorder specialists, a core physician target audience) have at some point been previously treated with IR amantadine (ADMS believes that 30%-50% of all treated PD patients have been on IR amantadine at some point), meaning that this kind of "soft" step edit does not in any way dramatically limit the underlying patient opportunity (i.e., though IR amantadine is not a standard-of-care treatment, it has seen sizable usage in PD patients moving through more advanced stages of the disease).

97. On Adamas' May 3, 2018 earnings call (the "May 2018 Call"), King again told an analyst on the May 2018 Call that payers were not requiring a "hard step" or "formal stepthrough IR amantadine:"

> DAVID A. AMSELLEM: …[A]re you surprised regarding the extent to which you are seeing patients having to be stepped through immediate release amantadine?...
>
> KING: So let me just try and pick up on the first point. You mentioned stepping through IR amantadine. I'm not aware of any plan that has a hard step for us through IR amantadine. I am aware of plans that have -- are interested as to whether IR amantadine's been tried before in patients and has been shown to either be ineffective or not well tolerated. We've seen that, but I'm unaware of any plan which has a formal stepthrough through IR amantadine.

98. FE5 explained that soft edits are when a payer requires the patient to have tried another medication, typically one that is less expensive and usually generic. FE5 said hard edits are when a payer wants the patient to not only try the generic, but to try that generic for a certain amount of time and sometimes up to a specific dose.

99. Regardless of the specific step through requirements, as detailed previously in Sections V.B & VI.B, *supra*, payers were requiring a step through of amantadine IR, including hard edits as defined by FE5. If patients had no prior history with amantadine or were unable to show it was ineffective or intolerable, they were required to try amantadine before these payers would

consider reimbursing GOCOVRI. Defendants' efforts to downplay these obstacles to reimbursement by claiming they were not "hard step" or a "formal stepthrough" support a strong inference that they were aware of the step through requirements when they claimed no payer to date had required them. Defendants were aware that news that payers were requiring step therapy would signal to the market that it lacked payer support, which would stymie demand for GOCOVRI given its price point. Defendants were also mindful that other payers, who were still evaluating their coverage requirements, would heed this revelation. Defendants' statements sought to assure the market that regardless of payers' reimbursement requirements, including step therapy, fulfillment was not an issue.

3. Defendants Tout Fulfillment & Physician Support In May 2018

100. On the May 2018 Call, King reported that "less than 2% of prescriptions received to date [are] ultimately rejected as not covered." King further stated during this call that "[w]e believe our GOCOVRI onboard program is effectively working to enhance physicians, patients and caregiver access to good healthy treatment when needed."

101. King also assured on the May 2018 Call that patients and physicians reported that treatment with GOCOVRI was a success, stating "[w]e're hearing loudly and clearly from these patients about the successes they are seeing with GOCOVRI treatment. Every day, we hear stories from our field team following meetings that they have had with physicians."

102. King continued to tout GOCOVRI's success with payers and physicians at the May 16, 2018 Bank of America investor conference (the "May 2018 Bank of America Conference"). King addressed an analyst's question about how Adamas was differentiating GOCOVRI from amantadine IR for physicians. King assured GOCOVRI was "very different to anything that's been seen before with IR amantadine" and that its "profile appears to resonate."

103. King also discussed OSMOLEX at the May 2018 Bank of America Conference, assuring that GOCOVRI had payer support because GOCOVRI had been differentiated from amantadine, and that such differentiation would be a struggle for OSMOLEX:

> And to date, payers have concluded that, that is a very different profile with GOCOVRI and IR amantadine and that, therefore, they will reimburse the product and support usage of it across the board, actually from a payer standpoint. I think

> with Osmotica's product, the challenge is going to be if what you are is potentially a more convenient IR amantadine, how do you justify that price point that you're charging for it against the value of the convenience between dosing once a day for the OSMOLEX product or 2 or 3 times a day for the IR product. I think that'll be an interesting challenge for them to face.
>
> * * * *
>
> [P]ayers have already made this assessment of how does GOCOVRI compare to IR amantadine. And concluded GOCOVRI is a better way to go with these patients without any additional clinical data…. And therefore, if you concluded to go with GOCOVRI for your Parkinson's dyskinesia patients compared to IR amantadine, can't quite (inaudible) the basis there would be to conclude to go with OSMOLEX as an alternative to GOCOVRI extension.

104. Also during the May 2018 Bank of America Conference, King made the assurance that "[r]eimbursement, whether you're Medicare or in the commercial environment, is occurring, and it's occurring with speed and support from the payer." King noted, "Quick Start is a very small minority of our patient population. So it gives you some sense as to how rapidly the payers are coming to conclusion."

105. Contrary to King's assertion, payers had not concluded GOCOVRI was a better way to go than amantadine IR. Indeed, the very paradigm King claimed OSMOLEX would face with respect to justifying its price point was precisely the payers' reaction to GOCOVRI.

106. Immediately after GOCOVRI's January 2018 launch, FE5 learned of reimbursement issues from physicians who complained about the length of time it was taking to fulfill. FE5 said most payers required prior authorization, which involved the doctor's description of the patient and why the patient required GOCOVRI. FE5 said some doctors also submitted a medical necessity letter. FE5 said these documents were submitted by the doctors through an online portal. FE5 explained that GOCOVRI's initial prior authorization period in which patients waited to hear from insurance companies took three to four weeks, and most of the time, it was declined. If the prior authorization was declined, FE5 said doctors would submit a medical necessity letter. FE5 said some insurance companies would submit the information about the patient to be peer-reviewed, but still ultimately denied reimbursement after the medical necessity letter was submitted. FE5 said the doctor could then appeal, which took another one to two weeks, but appeals were sometimes still

denied. FE5 said typically if there was a denial and an appeal was required, the physician would typically give up at that point.

107. FE4 similarly stated that fulfillment time was typically two to five weeks from the time the prescription was written, but some prescriptions took even longer. FE4 believed that prescriptions that were older than two months were unlikely to be filled at all but could not recall if there was a criteria setting the time when a prescription should be considered "dead" and thus not fulfilled.

108. FE5 said physicians in FE5's territory wrote approximately 100 prescriptions for GOCOVRI in the first quarter of 2018, but only about 20-30 were ultimately approved by the payers and fulfilled. FE5 said one physician initially wrote 20 prescriptions per week, but later decreased to a prescription rate of only one or two each month due to these access issues. FE5 said that by the second quarter of 2018, it was increasingly common for payers to require step therapy. FE5 believed that quickly after receiving the first several prescriptions and seeing the cost, the typical step was for payers to require that the patient try to generic first before the prescription will be filled. FE5 said an added problem was competition from OSMOLEX, which offered free samples and was better priced.

109. FE3 similarly noted that fulfillment issues, including step therapy requirements, began immediately after launch and only worsened over time. FE3 and other sales representatives reported these issues immediately after launch to FE3's Regional Manager on weekly conference calls who FE3 believed reported these issues up the chain. FE3 also learned from nurses and physicians immediately after launch that a large percentage of prescriptions were not filled because of GOCOVRI's high cost, and FE3 noted that other sales representatives reported the same issue.

110. FE1 described GOCOVRI as "a joke from the get-go" and similarly stated that the only distinguishing characteristic between GOCOVRI and generic amantadine was that it was administered in the evening. FE1 similarly indicated that the coverage and reimbursement picture was not as rosy as Defendants were portraying. FE1 stated that by May 2018 several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped

through amantadine IR. FE1 believed the step edits began with Blue Cross Blue Shield (*see* ¶86 (chart indicates that Blue Cross Blue Shield's decision to require an amantadine step through was made in December 2017 and January 2018)) and continued with the other payers. FE1 said UnitedHealthcare would not reimburse GOCOVRI at all.

111. FE1 said many prescriptions that were submitted for approval in Q1 2018 were never filled. FE1 said that by May 2018, fulfillment was taking as long as 30 days, which FE1 would not describe as quick. FE1 said the fulfillment delays were caused by requests for prior authorization and step edits, which contrary to Defendants' assurances, included not only confirming that the patient had already been on amantadine, but also, requirements that the patient try amantadine first. FE1 explained that due to these requirements there was a lot of paperwork that needed to be submitted before approval occurred, which further discouraged doctors from writing the prescriptions. FE1 noted that one physician who had initially written some prescriptions when GOCOVRI was first launched stopped prescribing it when the person in the physician's office who responsible for the paperwork stopped working there. In addition, FE1 indicated that a few months after the January 2018 launch, the Company was getting reports that patients were experiencing hallucinations and other tolerability issues. As a result of these reimbursement and tolerability issues, FE1 said patients were dropping-off GOCOVRI altogether, and physicians were writing fewer prescriptions.

112. FE6 said problems with fulfillment were noticed immediately after launch and there were daily discussions on how to streamline the process and reduce fulfillment time. FE3 and FE5 both said that offering GOCOVRI through a specialty pharmacy resulted in additional steps for patients and physicians and made access and distribution more difficult. FE3 was aware of these issues because FE3 assisted doctors and nurses in filling out the Onboard form and followed up with them when there were fulfillment issues noted in Tableau. FE4 said it was frustrating for doctors to have to go through varying processes for prescription approval for different drugs. FE1 recalled receiving a call from Cleveland Clinic wanting to directly order GOCOVRI, but Adamas would not direct ship any product. FE1 said other pharmacies were interested in distributing GOCOVRI, but

the Company decided to have only one specialty pharmacy. As such, FE1 believed that having only one specialty pharmacy limited GOCOVRI's distribution.

113. FE3 also indicated that the QuickStart program offered through Onboard was not enticing to physicians. FE3 said immediately after the January 2018 launch, physicians were requesting and indicating that they preferred free samples. FE3 said physicians preferred free samples to determine if GOCOVRI actually worked for patients before writing a prescription. FE3 said physicians' biggest concern was the cost, noting the big difference between GOCOVRI and generic amantadine, and said a large percentage of prescriptions were not filled due to the cost. FE3 also noted that patients were experiencing tolerability issues while taking GOCOVRI, including hallucinations which impacted sleep. FE3 explained that the impact on sleep was an issue since the main benefit of GOCOVRI was that it was supposed to lessen the sleep related side effects associated with amantadine.

114. FE2 indicated that physicians were not "super excited" about GOCOVRI, noting that neurologists treating these diseases are more interested in drugs that have "disease modifying properties" or slow down the advancement of the disease. FE2 found it difficult to differentiate the two drugs to physicians, likening the explanation of the difference between amantadine and GOCOVRI to explaining the difference between an aspirin and a coated aspirin but much more expensive. FE2 explained that Adamas had not conducted a head-to-head comparison of generic IR amantadine to GOCOVRI and noted that pharmaceutical companies typically want to avoid these types of comparison trials because they are costly, and the companies never know if the trial will produce significantly better results. FE2 also received reports from physicians that patients were experiencing sleep issues, including hallucinations, which FE2 claimed defeated the whole purpose of GOCOVRI.

115. FE2 also said doctors had to give patients with renal impairment a renal function test prior to prescribing, which involved additional time and cost and led to doctors being less inclined to prescribe the medication at all. FE2 said Patni was aware of physicians' issues with GOCOVRI from participating in weekly calls with the MSLs, or was informed by the manager of the MSLs.

FE2 believed Went was also aware of these issues because he worked closely with Patni and was closely involved in the clinical trials and in everything having to do with GOCOVRI.

116. FE6 similarly stated that market research indicated that doctors were confused about the difference between GOCOVRI and amantadine IR. FE6 said Went decided to change the sales message approximately three to six months after launch, which caused further confusion because there was not a consistent sales message.

4. Defendants Continue To Tout Payer & Physician Support & Patient Access on the Company's August 2018 Earnings Call

117. Despite the worsening payer landscape and widespread fulfillment and differentiation issues, King continued to tout support from payers on Adamas' August 2, 2018 quarterly earnings call (the "August 2018 Call"), stating: "We continue to see strong support from payers regarding GOCOVRI prescription reimbursement. The significant majority of submitted prescriptions to GOCOVRI onboard are being reimbursed in a short period of time." King also said that while Medicare had not issued formal guidance, Medicare patients were "getting reimbursement support from their plans, and it's happening quickly."

118. King also noted on the August 2018 Call that some physicians who were "taking a thoughtful approach" to GOCOVRI were doing so "largely based on their unsatisfactory historic experience with immediate-release amantadine in dyskinesia patients." King stated that physicians were "surprised" by the clinical data and wanted to see if "clinical benefits that we describe for GOCOVRI are as strong as our Phase III data illustrates."

119. As indicated above, this was not the case. In fact, FE1 claimed that by the summer of 2018, Adamas changed the way it compensated sales representatives as a result of fulfillment issues. When GOCOVRI was initially launched, commissions were paid based on enrollments alone, but in the summer of 2018 the Company changed the commission structure to be based on both enrollments and fulfillment. FE1 explained that enrollments were simply physicians submitting a form to Onboard, and by the summer of 2018 the Company noted that due to payers denying coverage and the lengthy fulfillment time resulting from the need to submit additional paperwork to meet increased reimbursement obstacles, many of these enrollments had not been

fulfilled. As such, Adamas was paying commission for enrollments which did not result in revenue. FE1 said King was ultimately fired because the enrollments did not bring in revenue.

120. FE5 said six to eight months after launch, the feedback from physicians was that they no longer wanted to write prescriptions due to the long reimbursement process, noting that payers were denying reimbursement and then denying the appeals. FE5 said even when reimbursement was provided, some patients were still expected to pay high co-pays that they could not afford, and so patients would not fill their prescriptions. FE5 said physicians were tired of having to "jump through hoops" to try to get approval and were frustrated by the long process and the low likelihood of approval so they did not want to waste their time.

121. FE6 said that approximately six months after launch, there were a significant number of physicians who initially wrote one or two prescriptions that had stopped writing new prescriptions. FE6 said efforts were being made to determine why that was the case. FE6 believed the long fulfillment time was a contributing factor, explaining that if a doctor had the experience of writing one or two prescriptions that were not approved, then those doctors were unlikely to continue writing prescriptions.

122. FE4 similarly stated that physicians who tried to obtain prior authorization, waited for approval, and were declined, were less interested in going through the process again for other patients. As such, FE4 said the Company not only lost that one patient, but all the patients that physician might have written prescriptions for.

123. FE4 noted that there was negative feedback on the use of specialty pharmacy, GOCOVRI Onboard, and the treatment form as part of the prescription fulfillment process. FE4 and FE6 said the use of a specialty pharmacy caused confusion, explaining that some doctors wrote typical prescriptions and patients then tried to fill them at a typical pharmacy, which could result in Adamas losing the prescription. FE6 said in the first six months there were a fair number of these prescriptions, but Adamas refused to even investigate how many prescriptions were potentially lost due to this confusion or how to correct the issue.

124. FE5 said these reimbursement and operational issues were discussed on the Sales Advisory Board conference calls with Hart, as well as with Went at an in-person meeting at Adamas'

California headquarters around the same time, in the summer of 2018.[10] FE5 said the Sales Advisory Board proposed several solutions to Went at that meeting, including offering free samples and providing sales representatives with more information about which payers were providing more coverage and which were providing less in order to prepare doctors. FE5 said they also recommended that Adamas make an effort to better educate payers about the difference between GOCOVRI and generic amantadine in order to avoid step therapy. FE5 said that Went indicated these suggestions would be considered, but did not implement any of them.

125. FE5 said Went told sales representatives to focus more on commercial payers where the reimbursement levels were higher; however, FE5 noted that most Parkinson's patients are older and on Medicare. FE5 explained that Medicare had an out of pocket maximum that was typically $900, which was a hardship for most patients to meet, thus stifling demand for GOCOVRI.

126. Still the market was unaware that payer requirements were impacting demand due to the Defendants repeated assurances. For example, Piper Jaffray issued a report on August 2, 2018 responding to the Company's Q2 2018 statements, describing access as "favorable":

> Regarding access, the payer landscape on the whole continues to be favorable, with most payers requiring what is essentially a "soft" step-edit where a physician need only attest that the patient has LID and has previously been on dopaminergic therapy (we take that to mean that it could be immediate-release (IR) amantadine or perhaps another dopamine agonist such as ropinirole).

D. The Truth Begins To Emerge

1. Defendant King Suddenly Departs Adamas For "Personal Reasons"

127. On September 14, 2018, Adamas filed a press release on Form 8-K with the SEC announcing that, on September 13, 2018, King "informed Adamas that effective September 15, 2018, he will depart from his position as Chief Operating Officer for personal reasons. Dean Hart, Senior Vice President of Sales, and Melissa Masterson, Senior Vice President of Commercial Operations and Market Access, will continue to lead the commercial efforts, reporting directly to Gregory Went, Chief Executive Officer." This announcement directly contradicted FE1's claim

[10] FE5 thought the in-person meeting was held in June 2018 but could only be certain that it was in the summer of 2018.

that King was fired because enrollments did not result in reimbursement.

2. An Analyst Report Detailing A Doctor Survey Reveals Weak Demand For GOCOVRI And High Levels Of Drop-Outs Due to Cost And Prior Authorizations

128. Just a few weeks later, on October 5, 2018, an analyst at Bank of America downgraded Adamas, revealing that a survey of doctors cast doubt on GOCOVRI's ability to achieve a sizable market share and showed a higher-than-expected dropout rate for GOCOVRI due to the high cost and difficulty in securing prior authorizations from payers:

> We conducted doctor checks with active prescribers who treat a total ~l.5k pts with Parkinson's disease (PD), of which ~700 are on generic amantadine IR and ~140 are on Gocovri. While this is a subset of total applicable physicians, their views are consistent with previous checks we have conducted this year. While respondents recognize the benefits of Gocovri over generic in reducing "off" time, better tolerability and lower pill burden (QD vs 3x a day), they note the hurdles to get patients on Gocovri due to cost (WAC [Wholesale Acquisition Cost]: $28.5k vs 2k for IR). The majority cited the need for prior authorization requests, with half noting requirement for prior treatment of generic. Doctors expect a moderate increase in Gocovri use in the next six months . . . . Gocovri is restricted on several formularies in 2019 (Express Scripts, CVS, United, Optum) but we note management in the past has stated to us that this is not in their view a deterrent to uptake.

129. The October 5, 2018 Bank of America analyst report also indicated that the drug's value proposition was not fully appreciated so the level of doctors' excitement was still in the middle range and it was taking longer than expected to become a "go-to-drug." Furthermore, the analyst noted looming competition from the pending initial public offering of Osmotica Pharmaceuticals, which planned to launch OSMOLEX in direct competition with GOCOVRI.

130. On this news, Adamas' stock fell $1.52 per share, or approximately 7.86%, to close at $17.83 on October 5, 2018.

3. Adamas Reveals Flat Prescription Growth And Cuts The Targeted Physicians In Half

131. On November 1, 2018, after the market close, Adamas held a quarterly earnings conference call (the "November 2018 Call") with investors. During this call, Went disclosed that the Company was substantially narrowing the physicians it was targeting, "focusing down on a little less than half of that 6,500 right now," but did not lower the Company's market share projections. Went further stated that the Company had "increased our understanding of market dynamics and we

are making adjustments and applying the learnings which we believe will lead to the prolonged success of GOCOVRI." Went explained that "we have long understood that GOCOVRI adoption in major movement disorder centers... is critical to our business.... [W]e are refining our execution and focusing our sales effort on these prescribers." However, the Company had always been focused on these prescribers, indeed King told investors on the August 2017 Call that the Company's education efforts were focused "particularly at the movement disorder specialist level." Thus, Went's statements during the November 2018 Call that Adamas was limiting its focus to movement disorder specialists revealed not only that GOCOVRI had failed to gain traction with general neurologists; but also, that despite the Company's focus on movement disorder specialists for well over a year, movement disorder specialists did not find GOCOVRI's value proposition enticing.

132. Despite having touted positive feedback from patients and physicians, Went also stated during the November 2018 Call that the Company would be "simplifying and strengthening our messaging for GOCOVRI as a treatment for dyskinesia as well as its benefits in OFF, highlighting the role GOCOVRI plays in widening the therapeutic window for dopamine treatments; and effectively educating physicians on appropriate use and appropriate patients for GOCOVRI." However, Adamas had been using this message to differentiate GOCOVRI from amantadine IR from at least since the beginning of the Class Period, thus indicating that physicians were not viewing GOCOVRI as differentiated, and which necessarily negatively impacted demand.

133. Went also stated on the November 2018 Call that the Company was "refining our communications regarding appropriate dosing," noting that "[d]osing can directly impact prescriber and patient experience with the medicine." Went stated that "patients with moderate to severe renal impairment, which can occur more often in the elderly, should start GOCOVRI at the 68.5-milligram dose to balance the efficacy with the tolerability, per GOCOVRI's label." As Went indicated, this was not new information, and was clearly indicated on GOCOVRI's label from the time the drug had been approved, revealing that patients were experiencing similar tolerability issues as experienced with amantadine IR, despite Defendants' touted positive feedback.

134. Also during the November 2018 Call, Merriweather told investors the Company was "intensely focused on increasing demand" and stated that the Company believed that

"approximately 2% market penetration on average for [2019] is an appropriate framework." Merriweather also revealed that new patient starts was "in that very same range quarter to quarter," reflecting that there had been no growth over the first three quarters following GOCOVRI's full commercial launch. Nevertheless, Went continued to assure that "market access and distribution are solid."

135. On all this news, Adamas' stock fell $5.08 per share, or 29.94%, to close at $11.89 per share on November 2, 2018.

136. Cowen issued a report on November 1, 2018 discussing the results, stating:

> [M]anagement indicates that the payer landscape and progress has been on-plan, as has been the effectiveness of the "Gocovri Onboard" program…. However, we provide two caveats, and unfortunately they are not insignificant. First, although management is providing total paid prescription figures, it is not disclosing the new prescriptions, which makes patient refill/retention impossible to calculate…. But second, and much more concerning, is that management indicated that "Due to patient starts generally at a consistent level over the last 2 quarters, we are intensely focused on increasing demand." We can come up with no good reason why patient starts were flat Q/Q and that trend is troubling if it persists. Management indicates that there is going to be a greater focus on the larger, major movement disorder centers, which we applaud but would have thought was obvious.

137. Nevertheless, some analysts remained optimistic based on Defendants' comments, as reflected in Piper Jaffray's report issued the same day, which stated GOCOVRI "is well-positioned for commercial success."

138. Went continued to tout the Company's prospects at the November 14, 2018 Credit Suisse investor conference, stating, "Our market access and distribution with our special -- single specialty pharmacy is going very well. And as we look forward at bringing this product to the market and educating the market on it and increasing the depth of its utilization, we anticipate that a 2019 performance is going to be a doubling of what we've seen in 2018." Evercore issued a report on December 12, 2018 after hosting meetings with management which noted, "ADMS continues to believe that sales/scripts will double next year."

4. Adamas Backs Off Previously Issued Guidance And Refuses To Provide Future Guidance

139. On March 4, 2019, after the market close, the Company held an earnings call (the

"March 2019 Call") to discuss fourth quarter and full year results for 2018 wherein Defendants revealed that they were backing off its 2% market share projection and would not be providing 2019 guidance.

140. As partially revealed in October 2018 by the Bank of America analyst and on the November 2018 Call, during the March 2019 Call, Went confirmed that demand was primarily limited to movement disorder specialists who used amantadine IR, whereas other neurologists had not differentiated GOCOVRI from amantadine. Went stated, "We have equipped our neurology account specialists with tools to distinguish between those movement disorder specialists that use amantadine as a part of their treatment toolbox and those who don't." Went noted, "we've seen strong adoption of GOCOVRI by the first group" but explained that the second group "does not typically use amantadine immediate release because in their experience, it is associated with limited efficacy and/or poor tolerability." Went indicated that "[f]or this latter group, we believe, based upon market research and confirmed through field feedback, that we need to more strongly emphasize the connection between dyskinesia and OFF time[.]" Went's statements also confirmed that payers' step-through requirements were an impediment to growth.

141. Went also announced on the March 2019 Call that QuickStart was being expanded to a 28-day program "to allow more prescribers and patients to readily experience first-hand the benefits of GOCOVRI." FE6 recalled discussions during his employment, which ended in November 2018, about lengthening Quick Start from 14 to 28 days to address the delays in fulfillment so that patients would continue to receive GOCOVRI while waiting for reimbursement. FE1 similarly stated that the decision to expand QuickStart to 28 days was due to the longer time it was taking to obtain approval from payers. FE4 said QuickStart was extended to 28 days due to frustration among physicians/patients and to improve operationally, noting that fulfillment typically took two weeks to five weeks, so the 28-day program was better for those patients for which it took longer than 14 days to get approval.

142. Went further explained during the March 2019 Call that the free trial expansion was a result of "listen[ing] to the field" and that the Company saw "that there were those physician's offices who were so accustomed to samples and other forms -- programs that would proceed their

reimbursement experience." The decision to expand the length of the Onboard program not only revealed that QuickStart was not designed to meet the needs of physicians and that physicians were not convinced by the clinical data that GOCOVRI was any different than amantadine IR; but also, that fulfillment time was not happening quickly and was taking longer than 14 days (the previous length of the Onboard free trial) due to payer requirements.

143. On the March 2019 Call, Went also stated that "[a]s we look back on the latter part of 2018, we specifically note a slowing in the rate of total prescription growth quarter-to-quarter, which we see continuing into the first part of 2019." Merriweather further added that "[b]ecause we're still very early in the commercialization of GOCOVRI, we are not providing prescription or revenue guidance in 2019."

144. During the question-and-answer portion of the March 2019 Call, an analyst asked, "should I take your comments to mean that you're backing off of your prior guidance that prescriptions or share would double?" Merriweather replied:

> As we look back from the end of last year, as I mentioned on the call, we did see a slower rate of increase in the TRx. And given that trend in the end of the fourth quarter and going into the first quarter, are not going to provide any specific TRx guidance this year or revenue guidance. So we'll continue to drive that growth through spreading the GOCOVRI message, broadening the GOCOVRI message around and it's typical early -- it's still in launch, we're really not in a position right now to guide for quarter-over-quarter for this year.

145. Likewise, during the March 2019 call, the analyst from Cowen and Company stated he was "really confused by the commentary. At this point, I would think enough clinicians had touched the product that we wouldn't have a slowing[.]" However, Adamas still had not revealed that payers were regularly denying reimbursement or requiring patients and physicians to "jump through hoops" to obtain reimbursement as indicated by FE5. While Went claimed the Company had "not noticed any differences in the beginning of the year with payer coverage," FE5 said step therapy had become more prevalent.

146. On this news, Adamas' stock fell $3.99 per share, or 32.84%, to close at $8.16 per share on March 5, 2019.

147. Piper Jaffray issued a report on March 4, 2019 titled, "Is Gocovri Being

Mismanaged? Sure Looks That Way." The report indicated the analyst had lowered its price target and stated that "[w]ith Adamas refining its marketing message on GOCOVRI, in addition to starting a sampling program over one year following the launch, it is fair to wonder if management has misread both its physician audience and the payer landscape."

148. Irina Koffler of Mizuho also downgraded Adamas to underperform and stated that she believed the launch to be going, "even worse than we thought."

149. On March 5, 2019, Cowen issued a report and downgraded Adamas to perform from outperform and cut the target price to $15 from $30. The report stated that management's own caution, "now raises many questions that we simply can't answer" and "We rarely see a company back away from guidance so quickly."

150. Bank of America published a report on March 5, 2019 stating, "the expansion of free drug to 28 day (prev. 14-day) in our view is a signal of weak demand consistent with our prior doctor checks which led to our initial round of estimate revisions last fall." The report noted that "coverage remains scarce with several national formularies excluding Gocovri in 2019."

5. Post Class Period, Adamas Confirms Weak Demand Was A Result Of Fulfillment Issues And GOCOVRI's High Cost

151. After the end of the Class Period, during an August 8, 2019 earnings call (the "August 2019 Call"), the Company confirmed that its inability to generate demand for GOCOVRI was due not only to its failure to differentiate it from amantadine IR, but also due to the burden of meeting payer requirements for reimbursement and operational issues with Onboard. These revelations corroborate the claims made by former employees that meeting payer requirements for reimbursement was suppressing demand, which was exacerbated by operational issues with Onboard. Contrary to prior representations that prescriptions were being fulfilled quickly, the Company admitted that patients were dropping off due to operational issues with fulfillment. Finally, the Company acknowledged that GOCOVRI's cost was a major factor inhibiting demand for the drug, contradicting prior claims that payers, physicians, and patients recognized the value proposition and that payers were providing strong support for reimbursement.

152. During this call, Adamas' new Chief Commercial Officer, Vijay Shreedhar,

introduced himself and explained what he has done to develop a "deep understanding" of Adamas' business, including visiting the specialty pharmacy to assess the operational elements of the fulfillment and distribution process, and speaking to the entire sales and commercial teams, and that his "interactions have also highlighted that we have work to do," listing "3 key areas where I will focus intensively[:]"

> First, we need to do a better job in educating healthcare practitioners to recognize the disruptive impact of dyskinesia, its relationship to OFF and its impact on the effective treatment of Parkinson's disease. While prevalent in patients treated with levodopa, dyskinesia is still relatively poorly understood or appreciated by both prescribers and patients. It is often confused with tremors and the impact that it may have on many aspects of a patient's daily life is not effectively highlighted. Educating healthcare practitioners on these aspects and on how to systematically identify appropriate patients for consideration of GOCOVRI therapy offers an opportunity for enhancing patient care.
>
> Second, based on my recent observations, there is an opportunity to improve our operational effectiveness in the fulfillment process. From the moment when a physician sends in a treatment form to when a patient gets the drug. I have noted some level of frustration among prescribers and we are working actively to address this and to improve the customer centricity of our overall fulfillment process to ensure that we create 1 that is simple, reliable and transparent.
>
> Third, we need to better educate a wider audience about our 28-day free trial program, which we hope will expand trial of the drug among non-adopters.

153. Went also commented on the Onboard process during his opening remarks on the August 2019 Call, stating that Adamas looked to "increase conversion by improving operational efficiencies with the process." Moreover, during the question-and-answer portion of the August 2019 Call, and in contradiction to Defendants' earlier claims that Onboard was working well and providing access rapidly, Shreedhar revealed that the burdensome process of submitting documents to obtain reimbursement along with operational issues with Onboard had impacted fulfillment and caused the vast majority of drop-offs:

> So we have done an analysis of patients who received drug through the free trial program in order to understand where the gaps were in them converting to maintenance scripts. The vast majority of patients actually drop-off because of operational considerations. There are prior authorizations that are still in process. There are steps that a physician's office needs to complete. There are steps that a patient themselves need to complete. That's where we believe we can have the most impact, which is why one of the focus areas that I articulated in terms of fulfillment

> focuses on the operational effectiveness to make it simpler and more transparent and reliable.

154. When asked to "get a little bit deeper into this fulfillment issue," Shreedhar described the fulfillment issues as "a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

155. Shreedhar was also asked about what he heard from non-adopters as their primary reason for not adopting GOCOVRI, to which Shreedhar explained "really boil down to 2 areas[:]" first, the "confusion around dyskinesia, how does it manifest? Is it bothersome?" and that this conversation happens between patients and physicians, and whether these conversations every few months was enough to identify the patients for consideration; and second "is cost and the perceptions of cost."

156. Lastly, during the August 2019 Call, Shreedhar fielded a question about the payer landscape and what needs to be done there, to which he indicated that prior authorizations were stymieing demand from physicians, and that Adamas was "evaluat[ing] contracting as a means to drive access to simplify the prior auth[orization] process to reduce physician burden in terms of process."

157. Cowen issued a report on August 8, 2019 reacting to this news, which stated:

> In addition, management disclosed "fulfillment issues" have been a significant component of the relatively low (40-50%) conversion of Gocovri free sampled patients to paying patients. They indicated that this low rate stems from what appears to be poor operations that are not allowing proper navigation of the managed care process and prior authorizations. This is causing frustration at the clinician and patient level. At this point in launch – and with this small number of patients and how critical the product is to the company, (and the amount of cash available to make the system work) – we are very surprised that this has still not been properly resolved.

158. These revelations corroborate the claims made by former employees that meeting payer requirements for reimbursement was suppressing demand, which was exacerbated by operational issues with Onboard. Contrary to prior representations that prescriptions were being fulfilled quickly, the Company admitted that patients were dropping off due to operational issues with fulfillment. Finally, the Company acknowledged that GOCOVRI's cost was a major factor inhibiting demand for the drug, contradicting prior claims that payers, physicians, and patients

recognized the value proposition and that payers were providing strong support for reimbursement.

159. While these revelations provided further insight into the causes of GOCOVRI's weak demand and the Company's failure to successfully launch, the market had already accounted for the lackluster demand when Adamas backed off its projections in March 2019. Adamas shares slightly increased, by 0.7%, on the news, from $6.01 per share on August 7, 2019 to $6.05 by August 9, 2019.

VII. DEFENDANTS' MATERIALLY FALSE AND/OR MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

A. Defendants' False And Misleading Statements And Omissions Prior to GOCOVRI's Full Commercial Launch

160. On August 8, 2017, Adamas held a quarterly earnings conference call wherein King answered an analyst question regarding the likelihood that payers would require a step-through of amantadine IR before reimbursing GOCOVRI (previously referred to as ADS-5102), stating:

> We've obviously done a fair amount of assessment of ADS-5102 with physicians and with payers. The profile for the product, as I mentioned in the comments, resonates extremely well. And **they don't see this profile as really having much to do with the amantadine IR profile** …. And that if ADS-5102 is approved for this indication, and with the clinical data set that is available to support it, that **there is no anticipation of requiring a step-through of amantadine IR to get to 5102**.

161. King's above statement emphasized in bold stating that, based on the Company's assessment with physicians and payers, "they don't see this profile as really having much to do with the amantadine IR profile," was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time King made this statement, Adamas had performed a quantitative study of physicians to gauge the demand and market size of GOCOVRI, and in response, some physicians commented that GOCOVRI sounded just like amantadine and other physicians responded that they were unlikely and unwilling to switch to GOCOVRI because they were already dosing generic amantadine like GOCOVRI to get the same result;

b. Adamas anticipated confusion between amantadine IR and GOCOVRI because GOCOVRI was in fact a reformulated version of amantadine;

c. By the time of this statement, an editorial written by Dr. Shukla had been published in the August 2017 JAMA. This editorial specified several important limitation of Adamas' EASE LID Study, including that "[t]here was no active comparison with immediate-release amantadine," and that until such a comparison was performed, it remained "unclear whether the potential benefits [of GOCOVRI] justify the costs[;]" and

d. By the time of this statement, an outside research firm had circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that payer support for pricing was driven down by the fact that GOCOVRI was a reformulation of the generic drug amantadine IR.

162. King's statement emphasized in bold in ¶160 stating that "there is no anticipation of requiring a step-through of amantadine IR to get to 5102," was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time of this statement, an outside research firm had both circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that regardless of the potential price points for GOCOVRI, certain payers indicated that they would impose access restrictions, including prior authorization and a step through of amantadine; and

b. Adamas always anticipated that some payers would require a step-through of amantadine, as confirmed by: (i) the former employee who was responsible for the commercial aspect of the GOCOVRI launch, FE4, who said that step therapy was accounted for in the Company's forecasts; (ii) Adamas' acknowledgement in its 2016-2018 10-Ks that payers' decisions are based in part on "the availability of generics available [to treat] similar indications[;]"and (iii) Defendant Went's later, November 1, 2018, admission while discussing challenges OSMOLEX would face in the market, including whether payers would first require patients to try amantadine IR, stating, "[b]ut again, … we're been facing that market reality since, well before we launder the product[.]"

163. On September 18, 2017, during Adamas' Investor & Analyst Meeting, in discussing

the pricing of GOCOVRI, King stated that after talking with payers, "what we concluded and what the **payers were willing to support us at was the GOCOVRI list price at $28,500 per year or $2,375 per month**[.]"

164. King's statement emphasized in bold above stating that payers were willing to support Adamas at the GOCOVRI list price of $28,500 per year or $2,375 per month was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, that by the time of this statement, an outside research firm had circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that payer support for pricing was driven down by the fact that GOCOVRI was a reformulation of the generic drug amantadine IR. These survey results also showed that payers preferred the lowest price range, and that regardless of the various price points for GOCOVRI that were presented to payers as part of the survey, certain payers indicated they would still impose reimbursement requirements (such as prior authorization and step-therapy).

B. Defendants' False And Misleading Statements And Omissions Regarding Payers' Requirement That Patients Step Through Amantadine IR To Access GOCOVRI

165. On January 22, 2018, Adamas filed a Form 8-K with the SEC, which included Adamas' updated risk factors. Therein, Adamas warned that the failure to successfully obtain coverage and reimbursement for GOCOVRI would diminish its ability to generate product revenue. Adamas further stated that:

> Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available. For example, **although no payer has done so to date,** a payer may determine to require patients to use other formulations of amantadine for dyskinesia (even though it is not approved for that indication) prior to receiving reimbursement for GOCOVRI.

166. The above statement emphasized in bold that "although no payer has done so to date" when explaining that a payer may require patients to use other formulations of amantadine prior to receiving reimbursement for GOCOVRI was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to

disclose, among other things, the following adverse facts:

a. By the time of this statement, and as of October 10, 2017, Centene had determined that, prior to providing reimbursement for GOCOVRI, failure of a 2-week trial of amantadine IR must be shown, unless amantadine IR was contraindicated, or clinically significant adverse effects were experienced upon trial of amantadine IR;

b. By the time of this statement, and as of November 16, 2017, Tricare had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate that it was both a medical necessity, meaning that the patient has experienced significant adverse effects to amantadine IR that are not expected to occur with GOCOVRI, and prior authorization, which involved the failure of a trial of amantadine IR tablets at least twice daily;

c. By the time of this statement, and as of November 17, 2017, Idaho Medicaid placed GOCOVRI on its formulary list as a non-preferred drug, which required failure of a preferred drug, including amantadine capsules, syrup, for prior authorization approval; and

d. By the time of this statement, and as of December 8, 2017, Blue Cross Blue Shield Federal Employees Program, had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate medical necessity, which required the prescribing physician to attempt adjusting levodopa therapy and to show that there was an inadequate treatment response or intolerance to short acting amantadine.

167. On February 22, 2018, Adamas issued its annual report of financial results for the fiscal year ended December 31, 2017 on SEC Form 10-K, and which was signed by Went and Merriweather. Therein, Adamas warned that the failure to successfully obtain coverage and reimbursement for GOCOVRI would diminish its ability to generate product revenue. Adamas further stated that:

> Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available. For example, **although no payer has done so to date,** a payer may determine to require patients to use other formulations of amantadine for dyskinesia (even though it is not approved for that indication) prior to receiving reimbursement for GOCOVRI.

168. The above statement emphasized in bold that "although no payer has done so to date"

when explaining that a payer may require patients to use other formulations of amantadine prior to receiving reimbursement for GOCOVRI was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time of this statement, and as of October 10, 2017, Centene had determined that, prior to providing reimbursement for GOCOVRI, failure of a 2-week trial of amantadine IR must be shown, unless amantadine IR was contraindicated, or clinically significant adverse effects were experienced upon trial of amantadine IR;

b. By the time of this statement, and as of November 16, 2017, Tricare had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate that it was both a medical necessity, meaning that the patient has experienced significant adverse effects to amantadine IR that are not expected to occur with GOCOVRI, and prior authorization, which involved the failure of a trial of amantadine IR tablets at least twice daily;

c. By the time of this statement, and as of November 17, 2017, Idaho Medicaid placed GOCOVRI on its formulary list as a non-preferred drug, which required failure of a preferred drug, including amantadine capsules, syrup, for prior authorization approval;

d. By the time of this statement, and as of December 8, 2017, Blue Cross Blue Shield Federal Employees Program had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate medical necessity, which required the prescribing physician to attempt adjusting levodopa therapy and to show that there was an inadequate treatment response or intolerance to short acting amantadine;

e. By the time of this statement, and as of January 24, 2018, Delaware Medicaid had listed GOCOVRI as a non-preferred agent for which prior authorization is required, and that before a non-preferred product would be approved, two preferred products must be tried. Delaware Medicaid included amantadine capsules, solution as a preferred agent; and

f. By the time of this statement, and during January 2018, Prime Therapeutics/Blue Cross Blue Shield of Alabama had determined that, prior to providing reimbursement for GOCOVRI, there must be prior authorization, including that (i) the patient's

medication history indicate the use of amantadine IR, or (ii) the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to amantadine IR.

169. On May 3, 2018, Adamas issued its quarterly report of financial results for the fiscal quarter ended March 31, 2018 on SEC Form 10-Q, and which was signed by Went and Merriweather. Therein, Adamas warned that the failure to successfully obtain coverage and reimbursement for GOCOVRI would diminish its ability to generate product revenue. Adamas further stated that:

> Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or cheaper therapeutic alternatives are already available or subsequently become available. For example, **although no payer has done so to date,** a payer may determine to require patients to use other formulations of amantadine for dyskinesia (even though it is not approved for that indication) prior to receiving reimbursement for GOCOVRI.

170. The above statement emphasized in bold that "although no payer has done so to date" when explaining that a payer may require patients to use other formulations of amantadine prior to receiving reimbursement for GOCOVRI was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time of this statement, and as of October 10, 2017, Centene had determined that, prior to providing reimbursement for GOCOVRI, failure of a 2-week trial of amantadine IR must be shown, unless amantadine IR was contraindicated or clinically significant adverse effects were experienced upon trial of amantadine IR;

b. By the time of this statement, and as of November 16, 2017, Tricare had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate that it was both a medical necessity, meaning that the patient has experienced significant adverse effects to amantadine IR that are not expected to occur with GOCOVRI, and prior authorization, which involved the failure of a trial of amantadine IR tablets at least twice daily;

c. By the time of this statement, and as of November 17, 2017, Idaho Medicaid placed GOCOVRI on its formulary list as a non-preferred drug, which required failure of a preferred drug, including amantadine capsules, syrup, for prior authorization approval;

d. By the time of this statement, and as of December 8, 2017, Blue Cross Blue Shield Federal Employees Program had determined that, prior to providing reimbursement for GOCOVRI, a patient must demonstrate medical necessity, which required the prescribing physician to attempt adjusting levodopa therapy and to show that there was an inadequate treatment response or intolerance to short acting amantadine;

e. By the time of this statement, and as of January 24, 2018, Delaware Medicaid had listed GOCOVRI as a non-preferred agent for which prior authorization is required, and that before a non-preferred product would be approved, two preferred products must be tried. Delaware Medicaid included amantadine capsules, solution as a preferred agent;

f. By the time of this statement, and during January 2018, Prime Therapeutics/Blue Cross Blue Shield of Alabama had determined that, prior to providing reimbursement for GOCOVRI, there must be prior authorization, including that (i) the patient's medication history indicate the use of amantadine IR, or (ii) the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to amantadine IR;

g. By the time of this statement, and during March 2018, Kaiser Permanente had determined that GOCOVRI will be covered on the prescription drug benefit when the patient has dyskinetic movement that have responded to an adequate trial (at least 4 weeks) of amantadine IR and the patient has failed amantadine IR due to frequency of dosing; and

h. By the time of this statement, and as of April 27, 2018, Vermont Medicaid had determined that, prior to providing reimbursement for GOCOVRI, the patient must have a documented side effect, allergy, or treatment failure with amantadine IR (defined as a decrease in effectiveness despite attempts to increase dosage to 300mg/day or by temporarily discontinuing amantadine for several weeks and restarting therapy).

C. Defendants' Materially False And Misleading Statements And Omissions Within The Risk Factors Listed In Adamas' Periodic Reports of Financial Results

1. Materially False And Misleading Statements And Omissions Within The Risk Factors Listed In Adamas' 10-Q For The Second Quarter of 2018

171. On August 2, 2018, Adamas issued its quarterly report of financial results for the

fiscal quarter ended June 30, 2018 on SEC Form 10-Q (the "2Q 2018 10-Q"), and which was signed by Went and Merriweather. Therein, Adamas warned that for distribution of GOCOVRI, "we are heavily dependent on third-party logistics, pharmacy and distribution partners. If they are unable to perform effectively or **if they do not provide efficient distribution of the medicine to patients, our business will suffer**."

172. The above statement emphasized in bold was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because that risk had already come to pass, as Adamas, Went, and Merriweather knew, or were deliberately reckless in not knowing, as demonstrated by the following adverse facts:

a. GOCOVRI was distributed through the Onboard specialty pharmacy which was unable to manage the operational burden of timely securing payer reimbursement requirements, including prior authorization, establishing medical necessity, and/or demonstrating patients had stepped-through amantadine;

b. By May 2018, and thus by the time of this statement, payer requirements for prior authorization and step therapy had resulted in fulfillment delays, taking as long as 30 days to fill a prescription, which was discouraging doctors from writing prescriptions. Adamas noticed these fulfillment delays immediately after the full commercial launch and there were daily discussions on how to streamline the process and reduce fulfillment time. As a result, fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients;

c. By the time of this statement, during the summer of 2018, due to fulfillment issues, Adamas had to change the way it compensated sales representatives from a compensation structure based on enrollments alone, to a compensation structure be based on both enrollments and fulfillment;

d. By the time of this statement, approximately six to eight months after GOCOVRI was fully launched, or from June 2018 to August 2018, physicians no longer wanted to write prescriptions due to the long reimbursement process, noting that payers were denying

reimbursement and then denying the appeals, and that even when reimbursement was provided, some patients were still expected to pay high co-pays that they could not afford, and so patients would not fill their prescriptions. Physicians were tired of having to "jump through hoops" to get payer reimbursement and were frustrated by the long process and the low likelihood of approval, and thus decided not to waste their time, not only for the current patient, but for every patient seen by that physician; and

e. As a result, the Company was unable to effectively distribute GOCOVRI which was harming its business.

173. The 2Q 2018 10-Q also warned that: "[a]s with any newly approved medicine for a particular indication, **there may be significant delays in obtaining final coverage and reimbursement decisions for GOCOVRI**."

174. The above statement emphasized in bold was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading because the risks had already come to pass, as Adamas, Went, and Merriweather knew, or were deliberately reckless in not knowing, as demonstrated by the following adverse facts:

a. By the time this statement was made, an outside research firm had both circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that regardless of the potential price points for GOCOVRI, certain payers indicated that they would impose access restrictions, including prior authorization and a step through of amantadine;

b. By the time of this statement, and as early as October 2017, payers were requiring step therapy and other reimbursement requirements to access GOCOVRI. Problems with fulfillment – largely resulting from payer reimbursement requirements – were noticed immediately after launch and there were daily discussions on how to streamline the process and reduce fulfillment time. By May 2018, several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped through amantadine IR. Adamas' former employees reported that by May 2018, requests for prior authorization and step therapy had resulted in

fulfillment delays, taking as long as 30 days to fill a prescription, which was discouraging doctors from writing additional prescriptions;

c. By the time of this statement, during the summer of 2018, due to fulfillment issues, Adamas had to change the way it compensated sales representatives from a compensation structure based on enrollments alone, to a compensation structure be based on both enrollments and fulfillment;

d. By the time of this statement, approximately six to eight months after GOCOVRI was fully launched, or from June 2018 to August 2018, physicians no longer wanted to write prescriptions due to the long reimbursement process, noting that payers were denying reimbursement and then denying the appeals, and that even when reimbursement was provided, some patients were still expected to pay high co-pays that they could not afford, and so patients would not fill their prescriptions. Physicians were tired of having to "jump through hoops" to get payer reimbursement and were frustrated by the long process and the low likelihood of approval, and thus decided not to waste their time, not only for the current patient, but for every patient seen by that physician;

e. By the time of this statement, in the summer of 2018, physicians' desire for free samples, market access and fulfillment issues detailed above were reported to Went at the Sales Advisory Board meeting held at the Company's corporate headquarters; and

f. As a result of the foregoing, the coverage and reimbursement paradigm was already negatively impacting the Company's ability to successfully commercial GOCOVRI.

2. Materially False And Misleading Statements And Omissions Within The Risk Factors Listed In Adamas' 10-Q For The Third Quarter of 2018

175. On November 2, 2018, Adamas issued its quarterly report of financial results for the fiscal quarter ended September 30, 2018 on SEC Form 10-Q, and which was signed by Went and Merriweather (the "3Q 2018 10-Q"). Therein, Adamas warned that "for distribution of GOCOVRI, we are heavily dependent on third-party logistics, pharmacy and distribution partners. If they are unable to perform effectively or **if they do not provide efficient distribution of the medicine to patients, our business will suffer**."

176. The above statement emphasized in bold was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because that risk had already come to pass, as Adamas, Went, and Merriweather knew, or were deliberately reckless in not knowing, as demonstrated by the following adverse facts:

a. GOCOVRI was distributed through the Onboard specialty pharmacy which was unable to manage the operational burden of timely securing payer reimbursement requirements, including prior authorization, establishing medical necessity, and/or demonstrating patients had stepped-through amantadine;

b. By May 2018, and thus by the time of this statement, payer requirements for prior authorization and step therapy had resulted in fulfillment delays, taking as long as 30 days to fill a prescription, which was discouraging doctors from writing prescriptions. Adamas noticed these fulfillment delays immediately after the full commercial launch and there were daily discussions on how to streamline the process and reduce fulfillment time. As a result, fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients;

c. By the time of this statement, during the summer of 2018, due to fulfillment issues, Adamas had to change the way it compensated sales representatives from a compensation structure based on enrollments alone, to a compensation structure be based on both enrollments and fulfillment;

d. By the time of this statement, approximately six to eight months after GOCOVRI was fully launched, or from June 2018 to August 2018, physicians no longer wanted to write prescriptions due to the long reimbursement process, noting that payers were denying reimbursement and then denying the appeals, and that even when reimbursement was provided, some patients were still expected to pay high co-pays that they could not afford, and so patients would not fill their prescriptions. Physicians were tired of having to "jump through hoops" to get payer reimbursement and were frustrated by the long process and the low likelihood of approval,

and thus decided not to waste their time, not only for the current patient, but for every patient seen by that physician; and

e. As a result, the Company was unable to effectively distribute GOCOVRI which was harming its business.

177. The 3Q 2018 10-Q also warned that: "[a]s with any newly approved medicine for a particular indication, **there may be significant delays in obtaining final coverage and reimbursement decisions for GOCOVRI**."

178. The above statement emphasized in bold was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading because the risks had already come to pass, as Adamas, Went, and Merriweather knew, or were deliberately reckless in not knowing, as demonstrated by the following adverse facts:

a. By the time this statement was made, an outside research firm had both circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that regardless of the potential price points for GOCOVRI, certain payers indicated that they would impose access restrictions, including prior authorization and a step through of amantadine;

b. By the time of this statement, and as early as October 2017, payers were requiring step therapy and other reimbursement requirements to access GOCOVRI. Problems with fulfillment – largely resulting from payer reimbursement requirements – were noticed immediately after launch and there were daily discussions on how to streamline the process and reduce fulfillment time. By May 2018, several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped through amantadine IR. Adamas' former employees reported that by May 2018, requests for prior authorization and step therapy had resulted in fulfillment delays, taking as long as 30 days to fill a prescription, which was discouraging doctors from writing additional prescriptions;

c. By the time of this statement, during the summer of 2018, due to fulfillment issues, Adamas had to change the way it compensated sales representatives from a compensation

structure based on enrollments alone, to a compensation structure be based on both enrollments and fulfillment;

d. By the time of this statement, approximately six to eight months after GOCOVRI was fully launched, or from June 2018 to August 2018, physicians no longer wanted to write prescriptions due to the long reimbursement process, noting that payers were denying reimbursement and then denying the appeals, and that even when reimbursement was provided, some patients were still expected to pay high co-pays that they could not afford, and so patients would not fill their prescriptions. Physicians were tired of having to "jump through hoops" to get payer reimbursement and were frustrated by the long process and the low likelihood of approval, and thus decided not to waste their time, not only for the current patient, but for every patient seen by that physician;

e. By the time of this statement, in the summer of 2018, physicians' desire for free samples, market access and fulfillment issues detailed above were reported to Went at the Sales Advisory Board meeting held at the Company's corporate headquarters; and

f. As a result of the foregoing, the coverage and reimbursement paradigm was already negatively impacting the Company's ability to successfully commercial GOCOVRI.

D. Defendants' False And Misleading Statements And Omissions In And Relating To Adamas' 1Q 2018 Financial Results

179. On May 3, 2018, Adamas held a quarterly earnings conference call with analysts and investors. During this call, King stated:

> [W]e are encouraged by the positive feedback from new patients on GOCOVRI. **We're hearing loudly and clearly from these patients about the successes they are seeing with GOCOVRI treatment.** Every day, we hear stories from our field team following meetings that they have had with physicians.

180. The above statement emphasized in bold was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading because it failed to disclose, among other things, the following adverse facts: by the time this statement was made, Adamas' sales force were reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting

demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price.

181. During the May 3, 2018 earnings call, King also assured that payers were supporting GOCOVRI, and that physicians and patients had access to the drug:

> Today, we've seen **support from payers** regarding GOCOVRI prescription reimbursement, a process which is handled by our GOCOVRI onboard program. The significant majority of prescriptions submitted are being reimbursed, with less than 2% of prescriptions received to date ultimately rejected as not covered.

182. Later during that same call, King told an analyst that "[t]o date, we have found that **we can get that access for patients reasonably straightforwardly**. Certainly, we're seeing the overwhelming majority of prescriptions filled, as I noted earlier on."

183. Also during this May 3, 2018 earnings call, King discussed QuickStart, stating, "Generally, **we're seeing reimbursement for prescriptions happen quickly**, which means that there's no need for the majority of patients for access to our QuickStart Program."

184. The statements emphasized in bold in ¶¶181-183 attesting to patient support and the straightforward access to GOCOVRI, and that Adamas and King were seeing prescription reimbursement happening quickly through QuickStart were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because payers did not "support" GOCOVRI, access for patients was not "reasonably straightforward[]," and reimbursement was not happening "quickly," as demonstrated by the following:

a. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement;

b. By the time these statements were made, due to the burdensome process of seeking reimbursement through Onboard and its related operational issues, as reported by multiple FEs, fulfillment times were so long that: (i) the 14 day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

185. King also answered an analyst's question during the May 3, 2018 earnings call about the extent to which patients were having to step-through amantadine IR, stating:

> So let me just try and pick up on the first point. You mentioned stepping through IR amantadine. **I'm not aware of any plan that has a hard step for us through IR amantadine. I am aware of plans that have -- are interested as to whether IR amantadine's been tried before in patients and has been shown to either be ineffective or not well tolerated. We've seen that, but I'm unaware of any plan which has a formal step through IR amantadine**.

186. King's above response in emphasized in bold claiming there was no "hard step" or "formal step" was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading because:

a. By the time this statement was made, payers were not only "interested" as to whether amantadine IR had been tried in patients, but as demonstrated by the chart of payer decisions in ¶86, required a showing that amantadine IR was not effective or well tolerated, and patients who were unable to make such a showing were required to undergo a course of treatment with amantadine IR, which was a "hard step" or "formal step though" in order to gain access to GOCOVRI;

b. By the time this statement was made, due to the burdensome process of seeking reimbursement through Onboard and its related operational issues, as reported by multiple FEs, fulfillment times were so long that: (i) the 14 day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on

August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

187. Finally, during the May 3, 2018 earnings call, King fielded a question about the portion of Adamas' LID patients who've been on a court of amantadine IR, responding, that although it was difficult to nail down the exact number, it was around the 50% mark or higher, and further commented that "**[a]nd we're not seeing that as a limitation to get access to GOCOVRI and the ultimate outcome**."

188. King's statement above emphasized in bold that amantadine IR was not a limitation to obtain coverage for GOCOVRI and the "ultimate outcome" for Adamas was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement;

b. By the time this statement was made, due to the burdensome process of seeking reimbursement through Onboard and its related operational issues, as reported by multiple FEs, fulfillment times were so long that: (i) the 14 day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

E. Defendants' False And Misleading Statements And Omissions During The May 16, 2018 Bank Of America Healthcare Conference

189. On May 16, 2018, Merriweather and King participated in the Bank of America Healthcare Conference. During the conference, King was asked to talk about the initial physician feedback the Adamas sales force has been receiving about how physicians are viewing the differences between GOCOVRI and amantadine IR. King responded that:

> We've made reference on our last quarterly call, somewhat unusual, I think, to actual commentary that we get back daily from our field team and directly from physicians about the impact that GOCOVRI has on people's lives… **So I think that feedback is positive, and it's animated. And that, I think, reinforces that physician trial, which gets them to go to a second patient and a third patient**. And as we kind of look at our adoption, what we see is sort of the time period between the first and the second prescription tends to be variable, can be short, can be long. But each subsequent prescription tends to get shorter and shorter between the second or the third, and third and the fourth. That time period shortens.

190. King's above statement emphasized in bold that the physician feedback the sales force had been receiving was positive and resulted in physicians prescribing GOCOVRI to additional patients in shorter time periods was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, the sales force was reporting that physicians were not "super excited" about GOCOVRI and did not view it as being differentiated from amantadine IR, confirming (i) Dr. Shukla's JAMA editorial that physicians would likely want to see a direct clinical comparison of GOCOVRI and amantadine IR given the drastic price difference between the two, and thus concluded that it remained to be seen if the "potential benefits [of GOCOVRI] justify the costs" based on its clinical studies, and (ii) market research indicating that physicians were confused about the difference between GOCOVRI and amantadine IR;

b. By the time this statement was made, Adamas' sales force was reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price; and

c. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients.

191. During the May 16, 2018 conference, the Bank of America analyst also asked about Adamas' differentiation efforts with physicians in distinguishing GOCOVRI from amantadine IR. King responded that:

> IR amantadine historically has been sort of -- it's not been the happy go-to drug for many physicians. It's difficult to find a risk-benefit profile that's acceptable to physicians with amantadine IR. It's -- at lower doses, it doesn't produce the desired effects, but it's an effort. It's not actually effective for the majority of patients. As you move up through the doses, you run into side effects, which tend to stop the majority of patients getting benefit from the drug. So there's just this very difficult to manage risk-benefit profile. We're at pains with GOCOVRI to point out a couple of things really. One, the PK profile for GOCOVRI is very, very different to anything that's been seen before with IR amantadine…. **[T]hat profile appears to resonate** and provide an efficacy profile, which, again, from our clinical studies, is very enticing to physicians.…

192. King's above statement emphasized in bold that the GOCOVRI profile was resonating with physicians was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, the sales force was reporting that physicians were not "super excited" about GOCOVRI and did not view it as being differentiated from amantadine IR, confirming (i) Dr. Shukla's JAMA editorial that physicians would likely want to see a direct clinical comparison of GOCOVRI and amantadine IR given the drastic price difference between the two, and thus concluded that it remained to be seen if the "potential benefits [of GOCOVRI] justify the costs based on its clinical studies, and (ii) market research indicating that physicians were confused about the difference between GOCOVRI and amantadine IR;

b. By the time this statement was made, Adamas' sales force was reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price; and

c. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients.

193. Also during the May 16, 2018 Bank of America Healthcare Conference, King touted payer support for GOCOVRI and the speed of reimbursement, stating: "Reimbursement, whether you're Medicare or in the commercial environment, is occurring, and it's occurring with **speed and support from the payer.**"

194. During this same conference King again indicated that payers were rapidly reimbursing GOCOVRI in the context of the minority of patients that used QuickStart while waiting for approval, stating, "that proportion of patients that's getting Quick Start is a very small minority of our patient population. So it gives you some sense as to **how rapidly the payers are coming to conclusion."**

195. The statements emphasized in bold ¶¶193-194 attesting to the speed and support from payers were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because reimbursement was not "occurring with speed and support from the payer" and payers were not "rapidly" coming to a conclusion, as demonstrated by the following:

a. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior

authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement;

b. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

196. During the May 16, 2018 healthcare conference, the Bank of America analyst also asked about competition from OSMOLEX, to which King admitted that there was some risk of confusion, but that it OSMOLEX is fundamentally a bioequivalent of amantadine IR, and elaborated on Adamas' to-date experience with payers' views of GOCOVRI to amantadine IR, stating:

> And to date, **payers have concluded that, that is a very different profile with GOCOVRI and IR amantadine and that, therefore, they will reimburse the product and support usage of it across the board**, actually from a payer standpoint.
>
> * * * *
>
> **[T]he payers have already made this assessment of how does GOCOVRI compare to IR amantadine. And concluded GOCOVRI is a better way to go with these patients without any additional clinical data.** I think the question, when you apply that same question to Osmotica, which is about 10x the price of IR amantadine, I'm going to -- some payers may decide to go there. But I think a difficult struggle to conclude that IR amantadine and Osmotica's product are different in anything other than dosage form or the dosage you take per day. And therefore, if you concluded to go with GOCOVRI for your Parkinson's dyskinesia patients compared to IR amantadine, can't quite (inaudible) the basis there would be to conclude to go with OSMOLEX as an alternative to GOCOVRI extension.

197. King's above statements emphasized in bold that payers have concluded that GOCOVRI has a very different profile than amantadine IR and that GOCOVRI was the better way to go were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time of this statement, an outside research firm had circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that payer support for pricing was driven down by the fact that GOCOVRI was a reformulation of the generic drug amantadine IR;

b. Adamas always anticipated that some payers would require a step-through of amantadine, as confirmed by: (i) the former employee who was responsible for the commercial aspect of the GOCOVRI launch, FE4, said that step therapy was accounted for in the Company's forecasts; (ii) Adamas' acknowledgement in its 2016-2018 10-Ks that payers' decisions are based in part on "the availability of generics available [to treat] similar indications[;]"and (iii) Defendant Went's later, November 1, 2018, admission while discussing challenges OSMOLEX would face in the market, including whether payers would first require patients to try amantadine IR, stating, "[b]ut again, … we're been facing that market reality since, well before we launder the product[;]" and

c. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement.

F. Defendants' False And Misleading Statements And Omissions In And Relating To Adamas' 2Q 2018 Financial Results

198. On August 2, 2018, Adamas held its quarterly earnings conference call. During King's opening comments he stated, "I am thrilled with the comments we continue to hear back from our field team and directly from physicians and patients…. **This positive reinforcement to the prescriber of the effects of a product is key to seeing continued and expanded usage by physicians over time.**"

199. King's above statement emphasized in bold that physicians and patients were providing "positive" feedback about the "effects" of GOCOVRI and was "key" to "continued and expanded usage by physicians over time" was materially misleading when made and/or omitted to state material facts necessary to make the statement not misleading, because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, the sales force was reporting that physicians were not "super excited" about GOCOVRI and did not view it as being differentiated from amantadine IR, confirming (i) Dr. Shukla's JAMA editorial that physicians would likely want to see a direct clinical comparison of GOCOVRI and amantadine IR given the drastic price difference between the two, and thus concluded that it remained to be seen if the "potential benefits [of GOCOVRI] justify the costs" based on its clinical studies, and (ii) market research indicating that physicians were confused about the difference between GOCOVRI and amantadine IR;

b. By the time this statement was made, Adamas' sales force was reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price; and

c. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients.

200. King also stated on the August 2, 2018 earnings call that "[w]e continue to see **strong support from payers regarding GOCOVRI prescription reimbursement**."

201. The above statement emphasized in bold indicating that GOCOVRI had "strong support from payers regarding GOCOVRI prescription reimbursement" was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not

misleading because it failed to disclose, among other things, the following adverse facts:

a. By the time of this statement, an outside research firm had circulated to and presented the results from a payer survey to Adamas employees, including Went and King, in or around July 2017. The survey results showed that payer support for pricing was driven down by the fact that GOCOVRI was a reformulation of the generic drug amantadine IR;

b. Adamas always anticipated that some payers would require a step-through of amantadine, as confirmed by: (i) the former employee who was responsible for the commercial aspect of the GOCOVRI launch, FE4, said that step therapy was accounted for in the Company's forecasts; (ii) Adamas' acknowledgement in its 2016-2018 10-Ks that payers' decisions are based in part on "the availability of generics available [to treat] similar indications[;]"and (iii) Defendant Went's later, November 1, 2018, admission while discussing challenges OSMOLEX would face in the market, including whether payers would first require patients to try amantadine IR, stating, "[b]ut again, … we're been facing that market reality since, well before we launder the product[;]" and

c. By the time this statement was made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement.

d. By the time this was made, several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped through amantadine IR.

202. During the question and answer portion of the August 2, 2018 earnings call, King first answered a question from an analyst regarding Adamas' ability to sustain the pace of growth of prescriptions per prescriber, stating that: "**as physicians move through that trial period, they become regular and continuous prescribers of GOCOVRI at that stage**.

203. King's above statement emphasized in bold attesting that "as physicians move through that trial period, they become regular and continue prescribers" was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, the sales force was reporting that physicians were not "super excited" about GOCOVRI and did not view it as being differentiated from amantadine IR, confirming (i) Dr. Shukla's JAMA editorial that physicians would likely want to see a direct clinical comparison of GOCOVRI and amantadine IR given the drastic price difference between the two, and thus concluded that it remained to be seen if the "potential benefits [of GOCOVRI] justify the costs" based on its clinical studies, and (ii) market research indicating that physicians were confused about the difference between GOCOVRI and amantadine IR;

b. By the time this statement was made, Adamas' sales force was reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price; and

c. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients.

204. Also during the question-and-answer portion of the August 2, 2018 call, King responded to an analyst's question as to whether price was a detractor for physicians:

> TAZEEN AHMAD: And also just on price, is that part of the discussion with physicians? …. But is that viewed as a detractor for physicians initially?
>
> RICHARD A. KING: **I wouldn't say that**….

205. King's above statement emphasized in bold indicating that price was not a detractor for physicians was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because it failed to disclose, among other things, the following adverse facts:

a. By the time this statement was made, the sales force was reporting that physicians were not "super excited" about GOCOVRI and did not view it as being differentiated from amantadine IR, confirming Dr. Shukla's JAMA editorial that physicians would likely want to see a direct clinical comparison of GOCOVRI and amantadine IR given the drastic price difference between the two, and thus concluded that it remained to be seen if the "potential benefits [of GOCOVRI] justify the costs" based on its clinical studies;

b. By the time this statement was made, Adamas' sales force was reporting that patients were experiencing the same negative sleep side effects associated with amantadine IR which was causing drop-offs and negatively impacting demand from physicians who now viewed GOCOVRI as lacking any benefit over amantadine to justify its substantially more expensive price; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that one of the "primary reasons for the poor adoption of GOCOVRI" was "cost and the perceptions of cost."

206. Also during the August 2, 2018 earnings call, King attested to the speed of payers' prescriptions reimbursements multiple times, stating:

a. "The significant majority of submitted prescriptions to GOCOVRI on board are being **reimbursed in a short period of time**[;]"

b. "[W]e continue to see current plans that have issued now formal guidance on how to process reimbursement for GOCOVRI. That continues to happen. There are still a number of plans that have not published those formal criteria yet. **But in the overwhelming majority of cases, we're seeing the vast majority of plans give us good support for reimbursement for GOCOVRI approval for reimbursement. And they're processing the prescription very, very quickly**, which is pleasing to us[;]" and

c. "**They're [Medicare patients] getting reimbursement support from their plans, and it's happening quickly**."

207. King's statements emphasized in bold in ¶206(a), (b), and (c) indicating that reimbursement or access was happening in a "short period of time" or "quickly" were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because they failed to disclose, among other things, the following adverse facts:

a. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement, all of which, according to former Adamas sales force employees, slowed down the reimbursement process;

b. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients; and

c. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

G. Defendants' False And Misleading Statements And Omissions In And Relating To Adamas' 3Q' 2018 Financial Results

208. On November 1, 2018, Adamas held a quarterly earnings conference call. During his opening remarks, Went referenced Onboard, calling it a "**seamless access experience provided by GOCOVRI Onboard**[.]"

209. During the question-and-answer portion of the November 1, 2018 earnings call, Went answered a question from an analyst regarding whether Adamas had observed changes in the step edits or prior authorization payer requirements, stating that they had not seen a change, and further offered: "**The prescriptions are being filled in a vast majority and they're being filled quickly**."

210. Defendant Went's statements during the November 1, 2018 earnings conference call emphasized in bold in ¶¶208-209 referring to Onboard as a "seamless access experience" and that prescriptions were being filled "quickly" were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because they failed to disclose, among other things, the following adverse facts:

a. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement, all of which, according to former Adamas sales force employees, slowed down the reimbursement process;

b. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients;

c. By the time this statement was made, several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped through amantadine IR; and

d. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians

were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

H. Defendants' False And Misleading Statements And Omissions At A November 14, 2018 Credit Suisse Investor Conference

211. On November 14, 2018, Went participated in and present at the Credit Suisse Healthcare Conference. During this conference, Went stated: "**Our market access and distribution with our special -- single specialty pharmacy is going very well**."

212. The above statement emphasized in bold that "market access and distribution... is going very well" was materially false and/or misleading when made and/or omitted to state material facts necessary to make the statement not misleading because they failed to disclose, among other things, the following adverse facts:

a. By the time these statements were made, payers were requiring a step through of amantadine IR or other reimbursement requirements, including medical necessity and/or prior authorization (as demonstrated by the chart of payer decisions in ¶86), denying reimbursement, and/or providing low levels of reimbursement, all of which, according to former Adamas sales force employees, slowed down the reimbursement process, and necessarily, the distribution process;

b. By the time this statement was made, Adamas' sales force was reporting that physicians were finding the process of seeking reimbursement through Onboard and its related operational issues burdensome and that fulfillment times were so long that: (i) the 14-day free supply of QuickStart was inadequate; (ii) patients were dropping off GOCOVRI; (iii) physicians were frustrated by the process, and as a result, were unwilling to write GOCOVRI prescriptions for their other patients;

c. By the time this statement was made, several payers who did not initially require step-therapy had determined that GOCOVRI was not that different from amantadine IR and were denying renewals and only providing reimbursement if the patient stepped through amantadine IR, and thus restricting market access; and

d. These problems were later confirmed when Defendants subsequently extended QuickStart to 28 days in March 2019, and admitted, after the end of the Class Period on August 8, 2019, that patients were dropping off GOCOVRI due to operational issues, physicians were frustrated by Onboard and the fulfillment process, which was described as "a white space a white space that exists between a physician sending in a treatment form and then finally getting confirmation that their patient is on drug."

VIII. LOSS CAUSATION

213. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic losses suffered by Plaintiff and the Class.

214. During the Class Period, Plaintiff and the Class purchased Adamas' securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed or materialized, causing investors' losses.

215. Artificial inflation in ADMS's stock price was removed when concealed risks partially materialized and/or the truth about the material misrepresentations and omissions was partially revealed to the public on October 5, 2018, November 1, 2018, and March 4, 2019. As a direct result of these partial disclosures, the price of Adamas' publicly traded securities declined precipitously on heavy trading volume, causing economic injury to Plaintiff and other members of the Class.

216. On October 5, 2018, Bank of America issued a report announcing that it had downgraded Adamas. As discussed at ¶¶128-129, the report revealed that a survey of doctors showed a higher-than-expected dropout rate for GOCOVRI due to the high cost and difficulty in securing prior authorizations from payers. It also noted that some payers were requiring prior treatment with generic amantadine IR. Not only were GOCOVRI dropouts occurring, but the drug's value proposition was not fully appreciated and was competition from OSMOLEX was looming. The Bank of America survey cast doubt on GOCOVRI's ability to achieve sizable market share.

217. On this news, Adamas' stock fell $1.52 per share, or approximately 7.86%, to close

at $17.83 on October 5, 2018, damaging investors.

218. On November 1, 2018, after the market closed, held an earnings conference call with investors. On this earnings call, Merriweather announced that the Company expected just 2% market penetration by the end of 2019, up from the then-expected 1% penetration by the end of 2018 (as detailed at ¶134). Went further explained that Adamas was narrowing its commercial efforts to focus on movement disorder center prescribers, and later explained that by doing so, sales efforts would focus on a "little less than half" of Adamas' previously number of targeted physicians. These announcements partially revealed that the rate of new prescribers was not as robust as the Company previously expected.

219. Also during the earnings call, Went explained that the Company had received feedback that elderly patients with renal impairment were experiencing tolerability issues. Because these same issues were experienced with amantadine IR, this announcement revealed that GOCOVRI did not have superior tolerability for these patients(as detailed at ¶133).

220. Following this news, Adamas' stock fell $5.08 per share, or 29.94%, to close at $11.89 per share on November 2, 2018, on heavy volume, damaging investors.

221. On November 1, 2018, the analyst firm Cowen explained that it remains cautious despite "[m]anagement indicat[ing] that the payer landscape and progress has been on-plan," because of two "not insignificant" caveats: first that management is "not disclosing the new prescriptions[;]" and "[s]econd, and much more concerning, is that management indicated 'Due to patient starts generally at a consistent level over the last 2 quarters, we are intensely focused on increasing demand.' We can come up with no good reason why patient starts were flat Q/Q and that trend is troubling if it persists. Management indicates that there is going to be a greater focus on the larger, major movement disorder centers, which we applaud but would have thought was obvious."

222. On March 4, 2019, after the market close, Defendants held an earnings conference call with investors and analysts to discuss Adamas' financial results for the fourth quarter and year ended December 31, 2018. During the opening comments, Went stated that the latter part of 2018 saw a slowing rate of total prescription growth quarter-to-quarter, and warned that this slowdown in prescription growth rate would continue "into the first part of 2019." In his opening comments,

Merriweather announced that "[b]ecause we're still very early in the commercialization of GOCOVRI, we are not providing prescription or revenue guidance in 2019." Went reiterated that Adamas would not be providing prescription or revenue guidance in response to an analyst question.

223. Went further explained that the Company was expanding Quick Start into a "broader free trial program," extending it from 14 to 28 days "to encourage trial of GOCOVRI in a broader array of patients" (as detailed in Section VI.D.4). The announcement disclosed that, contrary to prior statements, the 14-day period was inadequate due to: (i) long fulfillment times resulting in patient drop-offs, and frustrating physicians which negatively impacted demand for GOCOVRI; (ii) physicians' preference for free samples prior to writing prescriptions due to the lack of clinical data differentiating GOCOVRI to amantadine IR.

224. Following this news, Adamas' stock fell $3.99 per share, or 32.84%, to close at $8.16 per share on March 5, 2019, on heavy volume, damaging investors.

225. On March 4, 2019, Piper Jaffray lowered its price target for Adamas, concluding that "[w]ith Adamas refining its marketing message on GOCOVRI, in addition to starting a sampling program over one year following the launch, it is fair to wonder if management has misread both its physician audience and the payer landscape." Under the heading "Our confidence in management's ability to execute on Gocovri has been shaken[,] Piper Jaffray further found it "troubling" "that ADMS is only now initiating a sampling program when it could have done so right out of the gate."

226. On March 5, 2019, Cowen published a report entitled "Downgrade – Something Is Wrong And We Can't Figure It Out." Cowen concluded: "Reflecting management's removal of their previous qualitative guidance – and therefore lowering the growth trajectory – – downgrade is warranted. Cowen further noted that "We rarely see a company back away from guidance so quickly[,]" which "should obviously be [a] heightened concern."

227. Needham & Company similarly downgraded Adamas to hold and halved its price target to $15, on March 5, 2019, concluding: "Given the uncertainty and disruption of the ongoing Gocovri launch, we are heading to the sidelines … until we have better visibility that issues can be addressed[.]" The analyst firm Mizuho also downgraded Adamas to "underperform," slashing its price target to $5, explaining that it did not expect the company to "back away from prior 2019

outlook and believe[s] the launch is likely going even worse than thought."

228. Bank of America's March 5, 2019 report said that the expansion of the free trial was "a signal of weak demand consistent with our prior doctor checks which led to our initial round of estimate revisions last fall."

IX. ADDITIONAL SCIENTER ALLEGATIONS: GOCOVRI'S SUCCESSFUL LAUNCH WAS A CORE OPERATION

229. The fraud alleged herein relating to concealing the true state of affairs with respect to payer and physician support for GOCOVRI, and the success of GOCOVRI's commercial launch, all involved Adamas' core operation, and knowledge of the fraud may therefore be imputed to Defendants Went, Merriweather, and King.

230. Went was the founder of Adamas and conceived of the idea for GOCOVRI. Went oversaw its development and FDA approval. Following the FDA approval of GOCOVRI, Merriweather noted at the September 18, 2017 Investor & Analyst Meeting that it was "clearly a very important inflection point for Adamas as we transition from a company that's been focused on product development to a company that has a commercial opportunity and a pipeline of exciting new opportunities." GOCOVRI's commercial success was not only significant to Adamas' commercial success, but also, to validating the Company's development strategy of taking existing treatments and add a timing feature to them. On the February 22, 2018 earnings call, Went described GOCOVRI as "the most important proof point to date of our time-dependent biology approach."

231. As indicated in the Form 10-K for the year ending December 31, 2019 filed by Adamas on February 25, 2020, GOCOVRI was the primary source of revenue for the Company throughout the Class Period, representing 99% of its revenue in 2017, 2018, and 2019. The Company acknowledged in each of its annual reports filed on Form 10-K for the years ending December 31, 2016 through December 31, 2019 that, "Our success depends heavily on successful commercialization of GOCOVRI…. To the extent GOCOVRI is not commercially successful, our business, financial condition and results of operations will be materially harmed."

232. The significance of GOCOVRI's commercial success is further reflected by Went's deep involvement in the commercial organization after King's departure. FE4, as well as FE5,

reported directly to Went after King's departure, despite the Company publicly stating that Masterson and Hart would lead commercial efforts after King's departure. With King gone, Went led the commercial organization through the end of the Class Period and until Shreedhar joined the Company as Chief Commercial Officer on or around May 30, 2019.

A. Defendants Touted GOCOVRI's Differentiation & Value Proposition

233. The Defendants understood that differentiating GOCOVRI from amantadine IR, such that, patients, physicians, and payers appreciated the value proposition, was critical to commercial success. The Defendants repeatedly acknowledged this paradigm and assured investors that they had been successful in differentiating GOCOVRI from Amantadine IR, while knowing that was not the case based on the quantitative study of physicians to determine market demand and the pricing survey conducted with payers that Company had performed in the first half of 2017. On the May 2017 earnings call Went stated, "our research also indicated that payers appreciate the strong value proposition of ADS-5102" and assured that GOCOVRI "will be viewed as differentiated." On the August 2017 Call, King assured that GOCOVRI pricing would be "consistent with the value proposition for patients. And we believe we've got a strong value proposition, given the differentiated clinical nature of ADS-5102." Merriweather assured at the September 2017 Meeting that "we're also very comfortable… because of the clinical differentiation of the product getting up into that 25% to 30% at peak concentration of our target population."

234. Following GOCOVRI's commercial launch, the Defendants continued to claim GOCOVRI's value proposition was understood by physicians and payers and that they were viewing it as differentiated from amantadine IR. On the February 2018 Call, King assured that the OSMOLEX approval did not change the "value proposition" of GOCOVRI, noting "very strong, resonant support for GOCOVRI at both the physician and the payer level." King said that the number of prescribers "demonstrates the strength of the GOCOVRI value proposition for patients" on the May 2018 Call. King also assured GOCOVRI was "very different to anything that's been seen before with IR amantadine" and that its "profile appears to resonate." At the May 2018 Bank of America Conference, King noted, "payers have concluded that, that is a very different profile with GOCOVRI and IR amantadine and that, therefore, they will reimburse the product and support

usage of it across the board." King stated that OSMOLEX would have to "justify its price point" as it was merely a "more convenient IR amantadine," when in fact, GOCOVRI faced the same hurdles.

235. Defendants knew when these statements were made that: (i) payers had implemented step therapy requirements and were denying reimbursement or providing low levels of reimbursement; (ii) physicians were requesting free samples before writing prescriptions because the clinical data was insufficient to differentiate GOCOVRI from amantadine; and (iii) physicians were reporting to the Company that patients were experiencing the same tolerability issues as they had with amantadine IR. The repeated assurances support a strong inference of scienter.

B. Defendants Tracked GOCOVRI's Progress & Received Regular Feedback

236. The Defendants were heavily involved with the commercial launch of GOCOVRI and received regular progress reports. FE6 reported directly to Went and King at different times and detailed how Went fired consultants when he did not like the results of market research showing that many physicians would not switch to GOCOVRI because they viewed it as a reformulation of amantadine IR. Defendants King and Went also attended a presentation where the results of the Company's pricing survey of payers showed that regardless of the pricing tier, payers would require similar reimbursement restrictions, including step therapy.

237. Furthermore, Defendants' remarks about payer support were made in the context of discussions with payers. When King told investors on the August 2017 Call that physicians and payers "don't see this profile as really having much to do with the amantadine IR profile" and that there was "no anticipation" that payers would require a step through, he claimed it was based on his assessment with physicians and payers. When King discussed market access at the September 2017 Meeting, King said "we talked to 5 pharmacy benefit managers, 8 national-scale managed care organizations, 12 more regional managed care organization covering 125 million lives in the U.S." Masterson similarly noted that "about 20 payers cover about 85% of the lives in the United States" and assured "[w]e've already started discussion. We've already actually done a clinical presentation with one of the largest in the space." When King said "we anticipate broad coverage" on the November 2017 Call, it was in the context of "outreach to payers." And the Company's January 22, 2018 8-K stated that "Coverage and reimbursement discussions are currently ongoing with

payers" when it claimed that "no payer to date" was requiring a step through of amantadine IR. When King stated on the February 2018 Call that there was "very strong, resonant support for GOCOVRI at both the physician and the payer level" it was based on "presenting to the payer community and the physician community" for the past "4 or 5 months."

238. FE3, FE4, and FE6 detailed how Onboard's real time fulfillment data was available via Tableua dashboards to all executives at the level of Vice President and above, including the Defendants. In addition, the Defendants received monthly reports from Onboard with fulfillment data. The data showed the fulfillment status, fulfillment time, as well as the reasons why fulfillment had not occurred. FE6 said the primary benefit of using the specialty pharmacy was its ability to track this fulfillment data. FE4 & FE6 discussed fulfillment data with Went and King. FE4 further noted that Went was very involved and FE4 would be surprised if Merriweather was not familiar with the data because Adamas was such a small company.

239. FE5 said the purpose of the Sales Advisory Board, which consisted of sales representatives from each region, was to provide feedback on the sales and market access issues. The Sales Advisory Board met quarterly and reported to Hart who reported to Went. Went attended the meeting of the Sales Advisory Board at the Company's corporate headquarters in the summer of 2018 where sales representatives detailed the widespread market access and fulfillment issues that were impacting GOCOVRI. FE5 also indicated that Went was aware of the approval rate for GOCOVRI and instructed sales representatives to focus on patients covered by commercial payers as opposed to Medicare because the commercial payer approval rate was higher than Medicare's.

240. FE2 similarly stated that the MSLs collected doctors' feedback about GOCOVRI, which were reported to Patni at weekly meetings. FE2 also believed Went would have been aware due to his close working relationship with Patni. FE2 noted Adamas was a small company and Went developed the idea for GOCOVRI, was involved in the clinical trials, and everything have to do with GOCOVRI.

241. Not only did the Company specifically create these groups to receive feedback, but Defendants repeatedly touted the fact that they were receiving feedback. On the May 2018 Call, King stated, "Every day, we hear stories from our field team following meetings that they have had

with physicians." At the May 2018 Bank of America Conference, King similarly referenced "commentary that we get back daily from our field team and directly from physicians about the impact that GOCOVRI has on people's lives." King described patient and physician feedback as "animated" and "overwhelmingly positive" and claimed that it "just reinforces to physicians about the differentiation." On the August 2018 Call, King said, "I am thrilled with the comments we continue to hear back from our field team and directly from physicians and patients." However, the rosy picture Defendants painted for investors, according to the former employees, was contradicted the feedback that these groups were reporting. Defendants would subsequently cut the number of targets physicians in half and acknowledge the need to offer a broader free sample program as a result. The fact that groups that were developed to provide Defendants feedback, and Defendants told investors that they received positive feedback when in fact the feedback was anything but positive, supports a strong inference of scienter.

X. CORPORATE SCIENTER ALLEGATIONS

242. The Company is liable for the acts of the Individual Defendants and its other employees and agents under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment and/or agency.

243. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under the corporate scienter doctrine, *respondeat superior*, and agency principles.

XI. CLASS ACTION ALLEGATIONS

244. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of the Class, consisting of all individuals and entities that purchased or acquired Adamas shares between August 8, 2017 and March 5, 2019, inclusive, seeking remedies under Sections 10(b) and 20(a) of the Exchange Act. Excluded from the Class are Defendants, the officers and directors of the Company (at all relevant times), members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

245. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Adamas' shares were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Millions of Adamas shares were traded publicly during the Class Period on the NASDAQ. As of February 28, 2019, Adamas had 27,448,990 shares of common stock outstanding. Record owners and other members of the Class may be identified from records maintained by Adamas or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

246. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

247. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class action and securities litigation.

248. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Adamas;

c. whether Defendants knew or deliberately disregarded that their statements were false and misleading;

d. whether the price of Adamas securities were artificially inflated because of Defendants' conduct complained of herein; and

e. to what extent the members of the Class have sustained damages and the proper measure of damages.

249. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs complained of herein. Moreover, there will be no difficulty in the management of this action as a class action.

XII. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD- ON-THE-MARKET DOCTRINE)

250. The market for Adamas' shares was open, well-developed, and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Adamas' securities traded at artificially inflated prices during the Class Period. On January 23, 2018, the Company's shares closed at a Class Period high of $42.65 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's shares relying upon the integrity of the market price of Adamas' shares and market information relating to Adamas, and have been damaged thereby.

251. During the Class Period, the artificial inflation of Adamas' stock was caused by the material misrepresentations and/or omissions particularized in this Complaint, which in turn caused the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements and/or omissions about Adamas' business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Adamas and its business, operations, and prospects, thus causing the price of the Company's shares to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company's shares. Defendants' materially false and/or misleading statements and/or omissions during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's shares at such artificially inflated prices, and each of them has been damaged as a result.

252. At all relevant times, the market for Adamas' shares was an efficient market for the following reasons, among others:

a. Adamas stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Adamas filed periodic public reports with the SEC and/or the NASDAQ;

c. Adamas regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d. Adamas was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports were publicly available and entered the public marketplace; and/or

e. The average daily trading volume for Adamas securities during the Class Period was approximately 810,896 shares, with more than 27.5 million shares outstanding as of February 28, 2019, and a market capitalization reaching almost $1.1 billion during the Class Period.

253. As a result of the foregoing, the market for Adamas' shares promptly digested current information regarding Adamas from all publicly available sources and reflected such information in Adamas' stock price. Under these circumstances, all purchasers of Adamas' shares during the Class Period suffered similar injury through their purchase of Adamas' securities at artificially inflated prices and a presumption of reliance applies.

254. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misrepresentations and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of

the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XIII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

255. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the allegedly false statements pleaded in this Complaint.

256. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

257. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time of each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Adamas who knew that the statement was false when made.

XIV. CLAIMS

FIRST CLAIM
Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

258. Plaintiff repeats and re-alleges each allegation contained above as if fully set forth herein.

259. This claim is asserted against all Defendants and is based on Section 10(b) of the Exchange Act.

260. During the Class Period, the Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and

other members of the Class to purchase Adamas' shares at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, the Defendants took the actions set forth herein.

261. The Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares in an effort to maintain artificially high market prices for Adamas' shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All the Defendants were either primary participants in the wrongful and illegal conduct charged herein or were controlling persons as alleged below.

262. The Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Adamas' financial well-being and prospects, as specified herein.

263. The Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Adamas' value and performance and continued growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Adamas and its business operations and prospects, in light of the circumstances under which they were made, not misleading, and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares during the Class Period.

264. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of the Individual Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or

reports; (iii) each of the Individual Defendants enjoyed significant personal contact and familiarity with the other Individual Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, and operations at all relevant times; and (iv) each of the Individual Defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

265. The Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. The Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Adamas' financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by the Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, the Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

266. Because of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Adamas' shares was artificially inflated during the Class Period. In ignorance of the fact that the market price of the Company's shares was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the shares traded, and/or in the absence of material adverse information that was known to or recklessly disregarded by the Defendants, and not disclosed in public during the Class Period, Plaintiff and the other members of the Class acquired Adamas' shares during the Class Period at artificially high prices, and were damaged thereby.

267. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiff and the other

members of the Class and the marketplace known the truth regarding the Company's misrepresentations, which were not disclosed by the Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Adamas shares, or, if they had acquired such shares during the Class Period, they would not have done so at the artificially inflated prices which they paid.

268. Because of the foregoing, the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

269. As a direct and proximate result of the Section 10(b) Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and acquisitions of Adamas securities during the Class Period.

SECOND CLAIM
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

270. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

271. This claim is asserted against the Individual Defendants and is based on Section 20(a) of the Exchange Act.

272. The Individual Defendants acted as controlling persons of Adamas within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with, or had unlimited access to, copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

273. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular statements giving rise to the securities law violations as alleged herein and exercised the same.

274. As set forth above, Adamas and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. Because of their positions as controlling persons, the Individual Defendants are thus liable pursuant to Section 20(a) of the Exchange Act for Adamas' primary Exchange Act Section 10(b) violations. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's Shares during the Class Period.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) A determination that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) An award of compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained due to Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) An award to Plaintiff and the Class of their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

(d) Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: November 5, 2021

GLANCY PRONGAY & MURRAY LLP

By: *s/ Robert V. Prongay*

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Lead Counsel for Lead Plaintiff and the Class

PROOF OF SERVICE BY ELECTRONIC POSTING

I, the undersigned say:

I am not a party to the above case and am over eighteen years old. On November 5, 2021, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Northern District of California, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on November 5, 2021, at Los Angeles, California.

s/ Robert V. Prongay
Robert V. Prongay

EXHIBIT A

CENTENE® Corporation

Clinical Policy: Amantadine ER (Gocovri, Osmolex ER)

Reference Number: CP.PMN.89
Effective Date: 10.10.17
Last Review Date: 02.20
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Amantadine extended-release (Gocovri™, Osmolex ER™) is a weak uncompetitive antagonist of the N-methyl-D-aspartate (NMDA) receptor.

FDA Approved Indication(s)

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Osmolex ER is indicated for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Gocovri and Osmolex ER are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dyskinesia in Patients with Parkinson's Disease (must meet all)**:**

1. Diagnosis of dyskinesia in patients with Parkinson's disease;
2. Member is receiving levodopa-based therapy;
3. Meets one of the following (a or b):
   a. Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced;
   b. Medical justification supports inability to continue use of immediate-release amantadine (e.g., contraindications to excipients);
4. Dose does not exceed 274 mg per day for Gocovri or 322 mg per day for Osmolex ER.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Drug Induced Extrapyramidal Reactions (must meet all)**:**

1. Diagnosis of a drug induced extrapyramidal reaction;
2. Request is for Osmolex ER;
3. Meets one of the following (a or b):

a. Failure of a 2-week trial of immediate-release amantadine unless contraindicated or clinically significant adverse effects are experienced;
b. Medical justification supports inability to continue use of immediate-release amantadine (e.g., contraindications to excipients);

4. Dose does not exceed 274 mg per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., reductions in OFF time, improvement in dyskinesia symptoms);
3. If request is for a dose increase, new dose does not exceed 274 mg per day for Gocovri or 322 mg per day for Osmolex ER.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
amantadine immediate-release	Titrated up to 100 mg PO QID	400 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): end-stage renal disease
- Boxed Warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Amantadine ER (Gocovri)	Dyskinesia in Parkinson's disease	137 mg PO QHS for 1 week. After 1 week, increase to 274 mg (two 137 mg capsules) PO QHS	274 mg/day
Amantadine ER (Osmolex ER)	Dyskinesia in Parkinson's disease; drug induced extrapyramidal reaction	129 mg PO QAM, increase dose in weekly intervals	322 mg/day

VI. Product Availability

Drug Name	Availability
Amantadine ER (Gocovri)	Extended-release capsules: 68.5 mg and 137 mg
Amantadine ER (Osmolex ER)	Extended-release tablets: 129 mg, 193 mg, 258 mg

VII. References

1. Gocovri Prescribing Information. Emeryville, CA: Adamas Pharma, LLC; August 2017. Available at: https://www.gocovri.com/pdf/Gocovri_Prescribing_Information.pdf. Accessed October 30, 2019.
2. Osmolex ER Prescribing Information. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; July 2018. Available at: www.osmolex.com. Accessed October 30, 2019.
3. Oertel W, Eggert Karla, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). Mov Disord. 2017 August 21. Available at: 10.1002/mds.27131.
4. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson disease (EASE LID Study). JAMA Neurol. 2017;74(8):941-949. Doi:10.100/jamaneurol.2017.0943.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.10.17	01.18
Per SDC, added requirement for medical justification that supports inability to use immediate-release amantadine	04.12.18	
Added Osmolex ER per SDC based on approved clinical guidance; added criteria set for drug induced extrapyramidal reaction.	09.18.18	
1Q 2019 annual review; no significant changes; immediate-release amantadine two-week trial and medical justification requirements are edited to reflect either/or; references reviewed and updated.	11.13.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.30.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

EXHIBIT B

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 15 and 16, 2017, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August 2017 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the August 2017 DoD P&T Committee meeting on October 20, 2017, and signed the first and second addenda to the minutes on September 27 and October 19, 2017, respectively.

2. **Clarification to the August 2017 Minutes Implementation Dates:** The implementation dates for updated prior authorization criteria, quantity limits, line extensions, and the formulary status and prior authorizations for the newly-approved drugs per 32 CFR 199.21(g)(5) was changed to November 1, 2017.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

IV. UF DRUG CLASS REVIEWS

A. Weight Loss Agents

Background—Prior to the National Defense Authorization Act (NDAA) 2017, weight loss agents were excluded from the TRICARE pharmacy benefit. An Interim Final Rule published on September 29, 2017, (DOD-2017-HA-RIN 0720) "authorizes coverage under TRICARE

6. ***COMMITTEE ACTION: EMMPI REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not add the legend prenatal vitamins to the EMMPI program, and that the NF prenatal vitamins should be exempted from the NF mail order requirement due to feasibility issues related to the sheer number of products involved.

7. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 2, 2018.

V. NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5)

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix F for the complete list of newly-approved drugs reviewed at the November 2017 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, and see Appendix G for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- **UF**:
  - abemaciclib (Verzenio) – Oral Oncology Agents for Breast Cancer
  - belimumab (Benlysta) – Immunosuppressive Agents – Systemic Lupus Erythematosus
  - plasma-derived human C1 esterase inhibitor SQ injection (Haegarda)– Hereditary Angioedema (HAE)
  - enasidenib (Idhifa) – Oral Oncology Agents for Acute Myelogenous Leukemia
  - fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) – Pulmonary II Combination Agents – Chronic Obstructive Pulmonary Disease (COPD)
  - glecaprevir/pibrentasvir (Mavyret) – Hepatitis C Virus Direct Acting Antivirals (HCV DAAs)
  - L-glutamine (Endari) – Dietary Supplements
  - naldemedine (Symproic) – Gastrointestinal-2 Agents – Opioid Induced Constipation (OIC) Drugs
  - neratinib (Nerlynx) – Oral Oncology Agents for Breast Cancer
  - nitisinone (Nityr) – Metabolic Replacement Agents
  - perampanel (Fycompa oral solution) – Anticonvulsants/Anti-Mania Agents

- sofosbuvir/velpatasvir/voxilaprevir (Vosevi) – HCV DAAs

- **NF:**
  - amantadine ER (Gocovri) – Parkinson's Disease Drugs
  - betrixaban (Bevyxxa) – Oral Anticoagulants
  - delafloxacin (Baxdela) – Antibiotics – Quinolones
  - fluticasone propionate (ArmonAir RespiClick) – Pulmonary I Agents – Inhaled Corticosteroids
  - guselkumab (Tremfya) injection – Targeted Immunomodulatory Biologics (TIBs)
  - insulin aspart (Fiasp) – Insulins – Short-Acting Agents
  - lesinurad/allopurinol (Duzallo) – Antigout Agents – Chronic
  - methylphenidate ER orally dissolving tablet (Cotempla XR ODT) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
  - simvastatin oral suspension (FloLipid) – Antilipidemic-1s

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Gocovri, Bevyxxa, Baxdela, ArmonAir RespiClick, Tremfya, Fiasp, Duzallo, Cotempla XR ODT, and Flolipid. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same manual PA criteria for Tremfya in new users, as is currently in place for the other non step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Tremfya, a trial of both secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.

- Applying the same manual PA criteria to new users of Vosevi and Mavyret as is currently in place for the other non step-preferred DAAs for chronic hepatitis C infection. Harvoni is the preferred agent.

- Revising the manual PA criteria for Haegarda in new users to not allow concomitant use with another C1 esterase inhibitor product.

- Applying manual PA criteria to new users of Verzenio, Gocovri, Idhifa, Endari, Nerlynx, and Fycompa.

- Applying PA criteria to new and current users of Benlysta, ArmonAir RespiClick, Fiasp, Duzallo, Cotempla XR ODT, and FloLipid.

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	• Use of formulary agents and nonformulary agents (Qsymia, Contrave, Xenical, Belviq/Belviq XR) are contraindicated • Use of formulary agents and nonformulary agents (Qsymia, Contrave, Xenical, Belviq/Belviq XR) have resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• lorcaserin (Belviq, Belviq XR) • naltrexone SR/bupropion SR (Contrave) **Weight Loss Agents**	• Use of formulary agents is contraindicated • Use of formulary agent resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• orlistat (Xenical) **Weight Loss Agents**	• Use of formulary agents and nonformulary agents (Qsymia, Contrave, Belviq/ Belviq XR) is contraindicated • Use of formulary agents and nonformulary agents (Qsymia, Contrave, Belviq/ Belviq XR) have resulted in therapeutic failure • No alternative formulary agent: The patient is between 12 and 18 years of age **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• phentermine 8 mg tabs (Lomaira) **Weight Loss Agents**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• phentermine/topiramate ER (Qsymia) **Weight Loss Agents**	• Use of phentermine has resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• amantadine ER tablets (Gocovri) **Parkinson's Disease Drugs**	• The patient has experienced significant adverse effects to the formulary alternative amantadine IR that are not expected to occur with Gocovri. **Formulary Alternative:** amantadine immediate release
• betrixaban (Bevyxxa) **Oral Anticoagulants**	• No formulary alternative: The patient requires extended duration venous thromboembolism prophylaxis and cannot take SQ enoxaparin or SQ heparin due to adverse effects or therapeutic failure **Formulary Alternatives:** enoxaparin (Lovenox), SQ heparin
• delafloxacin (Baxdela) **Antibiotics: Quinolones**	• Use of formulary agents is contraindicated • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** ciprofloxacin and clindamycin, trimethoprim-sulfamethoxazole, linezolid, or any culture-sensitive agent(s)

Drug / Drug Class	Prior Authorization Criteria

• abemaciclib (Verzenio)
 	
Oral Oncologic Agents
	Manual PA criteria apply to all new users of Verzenio.
	
	Manual PA criteria—Verzenio is approved if:
	
	• The patient has a diagnosis of HR+, HER2 negative advanced or metastatic breast cancer
	• Breast cancer has progressed during or after endocrine therapy
	• The patient is using Verzenio and meets ALL of the following:
	  ○ Patient is postmenopausal and will use Verzenio in combination with fulvestrant OR
	  ○ The patient is premenopausal or perimenopausal and is receiving ovarian suppression with GnRH agonist AND Verzenio will be used in combination with fulvestrant OR
	  ○ Verzenio will be used as monotherapy and the patient has had prior chemotherapy for treatment of metastatic breast cancer
	
	Off-label uses are not approved
	Prior Authorization does not expire

• amantadine ER tabs (Gocovri) **Parkinson's Disease Drugs**	Manual PA criteria apply to all new users of Gocovri Manual PA Criteria—Gocovri is approved if: • The patient is ≥18 years old AND • Has a diagnosis of Parkinson's Disease AND • Has had therapeutic failure of a trial of amantadine 200 mg immediate release tablets administered twice daily Off label uses are not approved Prior Authorization does not expire
• belimumab (Benlysta) **Targeted Immunomodulatory Biologics (TIBs)**	Manual PA Criteria apply to all new and current users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta. Manual PA criteria: Coverage is approved for Benlysta if all of the following are met: • Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist • The patient is ≥18 years old • The patient has a documented diagnosis of active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE • The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • The patient does not have severe active lupus nephritis or severe active central nervous system lupus • The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide Off-label uses are not approved Prior Authorization expires in one year. Renewal PA Criteria: Benlysta will be approved on a yearly basis if all of the following are met: • Treatment with Benlysta has shown documented clinical benefit (i.e. improvement in number/frequency of flares, improvement in in Safety of

Appendix F—Formulary Recommendations for Newly-Approved Drugs Per 32 CFR 199.21(g)(5)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
abemaciclib (Verzenio)	Oncologic Agents: Breast Cancer CDK4/6	▪ palbociclib (Ibrance) ▪ ribociclib (Kisqali)	With fulvestrant HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine tx Monotherapy HR+, HER2- advanced metastatic breast cancer with disease progression following endocrine tx and prior chemo in metastatic setting	• 3rd CDK4/6 inhibitor available for HR+, HER2- advanced breast cancer • Demonstrated progression-free survival (PFS) benefit as single therapy in advanced therapy and in combination with fulvestrant for patients with life-threatening incurable disease • No overall survival benefit shown to date • Failed to show benefit in overall survival for *KRAS* mutated NSCLC • More selective for CDK4 than CDK6 • Side effects of neutropenia less severe than comparators, while more severe than comparators in diarrhea • Antidiarrheals coadministered at first sign of adverse event • Reduced neutropenia allows for continuous dosing	• UF • Do not add to EMMPI list
amantadine ER (Gocovri)	Parkinson's Disease Drugs	▪ amantadine immediate release	Dyskinesia with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications	• Amantadine may be considered to reduce dyskinesia (Level C) • May be appropriate for reducing nocturnal side-effects in patients who experience benefit from the immediate release but have insomnia or agitation	• NF • Exempt from NF mail order requirement due to feasibility (unavailable at mail order)
belimumab (Benlysta) SC	Immuno-suppressive Agents	▪ Standard therapy only (e.g., NSAIDS, corticosteroids, antimalarials, immuno-suppressives)	B-lymphocyte stimulator-specific inhibitor for adults with active, autoantibody-+ systemic lupus erythematosus (SLE) receiving standard therapy	• 1st biologic approved to treat SLE in conjunction with standard therapy • New SC formulation allows for patient self-administration at home; previous approved formulation given as monthly IV infusion in the clinic/hospital • Dosed 200 mg SC injection (not weight-based) in the abdomen or thigh, given once weekly • Studies for IV and SC formulations demonstrated similar efficacy and safety profiles, and superiority over placebo • Advantage over infusion for convenience, but lower response rate in African American women than placebo	• UF • Do not add to EMMPI list
betrixaban (Bevyxxa)	Oral Anti-coagulants	▪ apixaban ▪ rivaroxaban ▪ enoxaparin	Venous thromboembolism (VTE) prophylaxis in acutely hospitalized adults at risk for thromboembolic complications from moderate or severely restricted mobility and other risk factors for VTE	• 5th available direct acting oral anticoagulant (DOAC) • Only oral agent approved for VTE prophylaxis in acutely hospitalized patients • CHEST guidelines do not recommend extended duration VTE prophylaxis beyond hospitalization or period of immobility • Significantly increases bleeding risk without significantly decreasing VTE risk • No compelling advantage over existing UF agents	• NF • Exempt from NF mail order requirement (acute use)

EXHIBIT C

Idaho Medicaid Preferred Drug List Recommendations
November 20, 2017

Idaho Medicaid makes the following recommendations for the Idaho Medicaid Preferred Drug List. These recommendations are based on the clinical recommendations of the Pharmacy and Therapeutics Committee from the October 20 and November 17 meetings and take into consideration public and prescriber input, utilization patterns and cost data.

Therapeutic Class	Preferred Drugs	Non-Preferred Drugs
ALZHEIMER'S DRUGS CL	donepezil CL –except 23 mg tablets donepezil ODT CL EXELON (rivastigmine) transdermal CL memantine tablets CL rivastigmine capsules CL	donepezil 23 mg tablets CL galantamine tablets, solution CL galantamine ER CL memantine soln CL NAMENDA (memantine) XR CL NAMENDA (memantine) soln CL NAMZARIC (donepezil and memantine ER) CL rivastigmine transdermal CL
ANTI-ALLERGENS		GRASTEK (Timothy grass pollen allergen extract) CL ORALAIR (grass pollen extract-Cocksfoot, Sweet Vernal Grass, Rye Grass, Meadow Grass, Timothy) CL RAGWITEK (Short Ragweed pollen allergen extract) CL
ANTICONVULSANTS	<u>Adjuvants, Epilepsy</u> APTIOM (eslicarbazepine) CL divalproex sprinkle CL GABITRIL (tiagabine) CL levetiracetam solution, tablets CL oxcarbazepine suspension CL oxcarbazepine tablets CL topiramate sprinkles CL VIMPAT (lacosamide) tablets, soln CL zonisamide CL	BANZEL (rufinamide) tablets, suspension CL BRIVIACT (brivaracetam) tablets, soln CL felbamate tablets, suspension CL FYCOMPA (perampanel) tablets, suspension CL lamotrigine XR CL levetiracetam ER CL OXTELLAR XR (oxcarbazepine) CL SABRIL (vigabatrin) tablets, soln CL SPRITAM (levetiracetam) suspension CL tiagabine CL

ANTIHYPERURICEMICS	allopurinol probenecid	colchicine [CL] capsules, tablets MITIGARE (colchicine) capsules [CL] probenecid/colchicine [CL] ULORIC (febuxostat) [CL] ZURAMPIC (lesinurad)
ANTIPARKINSON'S DRUGS	amantadine capsules, syrup benztropine bromocriptine carbidopa/levodopa IR tablets carbidopa/levodopa ER carbidopa/levodopa/entacapone pramipexole IR ropinirole IR selegiline capsules, tablets trihexyphenidyl tablets, solution	amantadine tablet AZILECT (rasagiline) carbidopa carbidopa/levodopa ODT entacapone GOCOVRI (amantadine) MIRAPEX ER (pramipexole) NEUPRO (rotigotine) transdermal pramipexole ER rasagiline ropinirole ER RYTARY (carbidopa/levodopa ER) tolcapone XADAGO (safinamide) ZELAPAR (selegiline) disintegrating tablets
ANTIPSYCHOTICS	aripiprazole tablets chlorpromazine clozapine tablets FAZACLO (clozapine ODT) fluphenazine tablets, solution haloperidol LATUDA (lurasidone) loxapine olanzapine tablets olanzapine ODT ORAP (pimozide) perphenazine perphenazine/amitriptyline quetiapine tablets quetiapine ER risperidone solution, tablets, ODT thiothixene trifluoperazine ziprasidone capsules	aripiprazole disintegrating tablet aripiprazole solution clozapine ODT FANAPT (iloperidone) tablets molindone NUPLAZID (pimavanserin) olanzapine/fluoxetine (must use individual agents) paliperidone ER pimozide REXULTI (brexiprazole) SAPHRIS (asenapine) thioridazine VERSACLOZ (clozapine) VRAYLAR (cariprazine)

STIMULANTS AND RELATED DRUGS [CL]	ADDERALL XR (amphetamine salt combination) [CL] amphetamine salt combination IR [CL] APTENSIO XR (methylphenidate) [CL] atomoxetine clonidine IR FOCALIN (dexmethylphenidate) [CL] FOCALIN XR (dexmethylphenidate) [CL] guanfacine ER guanfacine IR methylphenidate IR tablets [CL] methylphenidate ER methylphenidate ER (generic for Concerta) [CL] methylphenidate ER (generic for Ritalin SR) [CL] QUILLICHEW ER (methylphenidate) [CL] QUILLIVANT XR (methylphenidate) solution [CL] VYVANSE (lisdexamfetamine) [CL]	ADZENYS XR ODT (amphetamine) [CL] amphetamine salt combination ER [CL] armodafinil [CL] CONTEMPLA XR-ODT (methylphenidate) clonidine ER [CL] DAYTRANA (methylphenidate) [CL] dexmethylphenidate [CL] dexmethylphenidate XR [CL] dextroamphtamine IR, ER [CL] dextroamphetamine solution [CL] DYANAVEL XR (amphetamine) [CL] EVEKEO (amphetamine) [CL] KAPVAY (clonidine ER) [CL] methylphenidate CD methylphenidate chewable tablets methylphenidate ER [CL] (generic Ritalin LA) methylphenidate solution [CL] modafanil [CL] MYDAYIS (amphetamine salt combination ER) NUVIGIL (armodafanil) [CL] PROCENTRA (dextroamphetamine solution) [CL] ZENZEDI (dextroamphetamine) [CL]
TOBACCO CESSATION	bupropion SR 150 mg CHANTIX (varenicline) [CL] nicotine gum OTC (nicotine polacrilex) nicotine lozenge OTC buccal (nicotine polacrilex) nicotine patch OTC (nicotine)	NICOTROL inhalation (nicotine) NICOTROL NS nasal (nicotine)

Note: Changes are indicated by highlighted area. Non-preferred drugs require failure of 1, 2 or 3 preferred agents for prior authorization approval. Those drugs with a [CL] also have clinical prior authorization criteria for use associated with them.

EXHIBIT D

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5.75.21

Section:	Prescription Drugs	**Effective Date:**	January 1, 2018
Subsection:	Neuromuscular Agents	**Original Policy Date:**	September 29, 2017
Subject:	Gocovri	**Page:**	1 of 4

Last Review Date: December 8, 2017

Gocovri

Description

Gocovri (amantadine)

Background

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy with or without concomitant dopaminergic medications. Motor problems and dyskinesia are significant complications of levodopa therapy used to treat patients with Parkinson's disease (PD) and increases in frequency the longer patients are treated with

levodopa for Parkinson's disease. Currently, treatment of dyskinesia related to Parkinson's disease includes adjusting levodopa doses and dosing schedule, adding additional medications to treat Parkinson's disease (thereby allowing for a decrease in the dose needed of levodopa) , and lastly adding a medication to specifically treat dyskinesia (amantadine) (1-2).

Regulatory Status

FDA approved indication:

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

Adverse reactions reported include: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, and impulse control/compulsive behaviors. Additionally, the use of this medication is contraindicated in patient with end-stage renal disease (below 15 mL/min/1.73 m_2) as this medication is primarily excreted renally (1).

Safety and effectiveness in pediatric patients have not been established (1).

5.75.21

Section:	Prescription Drugs	**Effective Date:**	January 1, 2018
Subsection:	Neuromuscular Agents	**Original Policy Date:**	September 29, 2017
Subject:	Gocovri	**Page:**	2 of 4

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gocovri may be considered **medically necessary** for patients 18 years of age or older with Parkinson's disease (PD), receiving levodopa therapy and experiencing dyskinesia when the conditions below are met.

Gocovri may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease (PD)

a. Patient is experiencing dyskinesia

AND ALL of the following:

1. Currently receiving levodopa-based therapy
2. Documented baseline evaluation of dyskinesia
3. Prescribing physician has attempted to adjust levodopa therapy to decrease dyskinesia
4. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following adjunctive pharmacotherapy options:
   a. Dopamine agonists
   b. COMT inhibitors
   c. MAO B inhibitors
5. Inadequate treatment response or intolerance to short acting amantadine
6. **NO** end-stage renal disease (ESRD)

5.75.21

Section:	Prescription Drugs	**Effective Date:**	January 1, 2018
Subsection:	Neuromuscular Agents	**Original Policy Date:**	September 29, 2017
Subject:	Gocovri	**Page:**	3 of 4

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Parkinson's disease (PD)

a. Patient is experiencing dyskinesia

AND ALL of the following:

1. Currently receiving levodopa-based therapy
2. Documented improvement in dyskinesia from baseline
3. **NO** end-stage renal disease (ESRD)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity	68.5 mg	180 capsules per 90 days **OR**
	137 mg	180 capsules per 90 days
	Maximum daily limit of any combination: 274 mg	
Duration	12 months	

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy with or without concomitant dopaminergic medications. Motor problems and dyskinesia are significant complications of levodopa therapy used to treat patients

with Parkinson's disease (PD), and increases in frequency the longer patients are treated with levodopa for Parkinson's disease. Adverse reactions reported include: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, and impulse control/compulsive behaviors (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Gocovri while maintaining optimal therapeutic outcomes.

References

1. Gocovri [package insert]. Emeryville, CA: Adamas Pharma, LLC.; August 2017.
2. Daniel Tarsy. Motor fluctuations and dyskinesia in Parkison disease. UpToDate. March 23, 2017.

Policy History

Date	Action
February 2017	Addition to PA
December 2017	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2017 and is effective on January 1, 2018.

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EXHIBIT E

2018
Delaware Preferred Drug List (PDL)

Contents

ANTIPARKINSON'S AGENTS, ORAL/TRANSDERMAL

PREFERRED AGENTS		NON-PREFERRED AGENTS		CRITERION
Preferred status implementation: 1/1/18		Prior authorization is required		
amantadine capsules, solution	ropinirole IR	amantadine tablets	selegiline capsules	Two preferred products required before a non-preferred product will be approved
benztropine	selegiline tablets	entacapone	tolcapone	
carbidopa/levodopa IR, ER	trihexyphenidyl	bromocriptine	Duopa	
pramipexole IR		carbidopa	Gocovri[NR]	
		carbidopa/levodopa ODT	Neupro	
		carbidopa/levodopa/ entacapone	Rytary	
		pramipexole ER	Xadago[NR]	
		ropinirole XL	Zelapar	

SKELETAL MUSCLE RELAXANTS

PREFERRED AGENTS		NON-PREFERRED AGENTS		CRITERION
Preferred status implementation: 1/1/18		Prior authorization is required		
baclofen		carisoprodol ●	metaxalone	Two preferred products required before a non-preferred product will be approved
chlorzoxazone		carisoprodol compound	orphenadrine	
cyclobenzaprine 5, 10 mg		carisoprodol compound w/codeine ●	tizanidine capsules	Total quantity limit of 120 units of muscle relaxants per 30 rolling days.
methocarbamol		cyclobenzaprine 7.5 mg	Amrix	
tizanidine tablets		cyclobenzaprine ER	Lorzone	●–Clinical PA required
		dantrolene		http://medicaidpublications.dhss.delaware.gov/dotnetnuke/search?Command=Core_Download&EntryId=177

EXHIBIT F

BlueCross BlueShield of Alabama

Gocovri™ (amantadine) Prior Authorization with Quantity Limit Program Summary

This prior authorization applies to Commercial, NetResults A series, SourceRx and Health Insurance Marketplace formularies.

OBJECTIVE
The intent of the Gocovri Prior Authorization (PA) Criteria is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies and according to dosing recommended in product labeling.

TARGET AGENT
Gocovri ™ (amantadine)

QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity Limit
Gocovri (amantadine) extended release			
68.3 mg capsules	73200010107020	M, N, O, or Y	1 capsule
137 mg capsules	73200010107040	M, N, O, or Y	2 capsules

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Gocovri (amantadine) will be approved when ALL of the following are met:

1. The patient has a diagnosis of Parkinson's disease
   AND
2. The requested agent will be used for the treatment of dyskinesia
   AND
3. The prescriber is a specialist (e.g. neurologist) or the prescriber has consulted with a specialist
   AND
4. The patient is currently receiving levodopa therapy
   AND
5. ONE of the following:
   A. The patient's medication history indicates the use of immediate release amantadine **OR**
   B. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immediate release amantadine
   AND
6. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
   AND
7. ONE of the following
   A. The requested quantity (dose) is NOT greater than the program quantity limit
   OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is less than or equal to the FDA labeled dose
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

OR

C. ALL of the following:
   i. The requested quantity (dose) is greater than the program quantity limit
   AND
   ii. The requested quantity (dose) is greater than the FDA labeled dose
   AND
   iii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

FDA APPROVED INDICATION AND DOSAGE[1]

Agent	Indications	Dose
Gocovri™ (amantadine)	Treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications	Initial dose: 137 mg orally daily at bedtime, after one week increase to recommended daily dose Maintenance dose: 274 mg orally daily at bedtime

CLINICAL RATIONALE

Parkinson's disease (PD) is a chronic, progressive movement disorder that affects at least one–half million patients across the United States.[2] PD belongs to a group of conditions called motor system disorders, which are the results of loss of dopamine-producing brain cells. The four primary symptoms of PD are tremor, or trembling in hands, arms, legs, jaw, and face; rigidity, or stiffness of the limbs and trunk; bradykinesia, or slowness of movement; and postural instability, or impaired balance and coordination. PD usually affects those over the age of 60. Early symptoms of PD are subtle and occur gradually and may progress more quickly in some people than others. Other symptoms may include depression and other emotional changes; difficulty swallowing, chewing, and speaking; urinary problems or constipation; skin problems; and sleep disruptions. Diagnosis is based on medical history and neurological examinations.[3]

There is no cure for PD and management of PD requires consideration of patient's symptoms, age, stage of disease, degree of functional disability, and level of physical activity and production. Treatment options can be divided into pharmacologic, non-pharmacologic, and surgical therapy. Pharmacologic treatment of PD can be further divided into neuroprotective and symptomatic therapy. Treatment of advanced PD, particularly the complications associated with long-term levodopa therapy, and management of the comorbid problems including daytime sleepiness, hallucinations, and psychosis. Agents available for the treatment of PD motor symptoms include levodopa, dopamine agonists, monoamine oxidase (MAO) B inhibitors, anticholinergic agents, amantadine, and catechol-O-methyl transferase (COMT) inhibitors.[4]

Levodopa or a dopamine agonist can be used as initial therapy for patients who require symptomatic therapy for PD. Levodopa is the most effective drug for the symptomatic treatment of PD and is the first choice if symptoms, particularly related to bradykinesia, become intrusive or troublesome. Dopamine agonists may be employed as either monotherapy in early PD or in combination with other antiparkinsonian drugs for the treatment of more advanced disease. They are ineffective in patients who do not show response to levodopa. Dopamine agonists may be associated with fewer motor fluctuations than levodopa and there is a higher incidence of levodopa related dyskinesia in young-onset PD. Given this, dopamine agonists are reasonable initial therapy for younger patients (age <65 years) and with levodopa in older patients (age >65 years).[4]

Although initially effective, dopaminergic therapies are eventually complicated by motor fluctuations and dyskinesia. Motor fluctuations include off time, where periods of when the medication wears off and the PD symptoms appear. Dyskinesia is defined as drug-induced involuntary movements including chorea and dystonia. The motor complications can impair the quality of life and cause significant disability. Risk factors for motor complications

include younger age at onset of PD, disease severity, higher levodopa dosage, and longer disease duration. Motor complications are usually addressed with levodopa adjustments and the addition of adjunctive medications. Motor fluctuations and dyskinesia can be resistant to medical therapy.[5]

Anticholinergic drugs are most useful as monotherapy in patients under 70 years of age with disturbing tremor who do not have significant bradykinesia or gait disturbance. They also may be useful in patients with more advanced disease who have persistent tremor despite treatment with levodopa or dopamine agonists. Their use in older or demented individuals and those without tremor is strongly discouraged.[4]

Amantadine may be considered for patients with PD with motor fluctuations in reducing dyskinesia.[5] Amantadine is a relatively weak antiparkinsonian drug with low toxicity that is most useful in treating younger patients with early or mild PD and perhaps later when dyskinesia becomes problematic. However, toxic side effects are more likely in older patients.[3] Amantadine in divided doses of 200 to 400 mg a day may reduce the intensity of levodopa-related dyskinesia and motor fluctuations in patients with PD. Although the published randomized trials on amantadine in advanced PD are limited by serious methodological flaws and small numbers of patients, experience has shown that individual patients with advanced PD who have motor fluctuations and dyskinesia can benefit dramatically, at least for a while, from the addition of amantadine to a regimen of levodopa. Furthermore, a randomized controlled trial of 56 patients with PD and levodopa-related dyskinesia found that withdrawal compared with continuation of amantadine led to significant worsening of dyskinesia.[4]

Safety[1]

The most common adverse reactions reported in >10% of GOCOVRI-treated patients and more frequently than on placebo were: hallucination, dizziness, dry mouth, peripheral edema, constipation, falls, and orthostatic hypotension.

The overall rate of discontinuation because of adverse reactions for GOCOVRI-treated patients was 20%, compared to 8% for placebo-treated patients. Adverse reactions that led to treatment discontinuation in at least 2% of patients were hallucination (8% GOCOVRI vs. 0% placebo), dry mouth (3% GOCOVRI vs. 0% placebo), peripheral edema (3% GOCOVRI vs. 0% placebo), blurred vision (GOCOVRI 3% vs. 0% placebo), postural dizziness and syncope (GOCOVRI 2% vs. 0% placebo), abnormal dreams (GOCOVRI 2% vs. 1% placebo), dysphagia (GOCOVRI 2% vs. 0% placebo), and gait disturbance (GOCOVRI 2% vs. 0% placebo).

Gocovri is contraindicated in patients with end-stage renal disease (i.e., creatinine clearance below 15 mL/min/1.73 m^2). There are several warning and precautions within FDA approved label including suicidality and depression, hallucinations/psychotic behavior, dizziness, orthostatic hypotension, withdrawal-emergent hyperpyrexia, compulsive behavior, and somnolence.

REFERENCES

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2. National Institute of Neurological Disorders and Stroke. Focus on Parkinson's Disease Research. www.ninds.nih.gov.
3. American Academy of Neurology. Parkinson's Disease. American Academy of Neurology Foundation. 2017. Accessed at: http://patients.aan.com/disorders/?event=view&disorder_id=1029. Accessed on February 21, 2017.

4. Tarsy, Daniel, MD, Hurtig, Howard, MD, Dashe, John, MD, PhD. Pharmacologic Treatment of Parkinson's Disease. UpToDate. Topic 4896, Version 32.0. Last updated August 2017.
5. Pahwa, R, MD, et al. Practice Parameters: Treatment of Parkinson Disease With Motor Fluctuations and Dyskinesia (An Evidenced Based Review). *Neurology*. April 11, 2006: 66 (7); 983-995.

EXHIBIT G

Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Amantadine ER (Gocovri ™)

Non-formulary **amantadine ER (Gocovri™)** will be covered on the prescription drug benefit when the following criteria are met:

* Prescribed by a neurologist with expertise in diagnosis/treating Parkinson's Disease

- AND –

* Diagnosis of Parkinson's Disease on problem list

-AND-

* Pt currently prescribed carbidopa/levodopa 3 times per day or more

-AND-

* Pt has dyskinetic movements that have responded to adequate trial (≥4 week) of amantadine IR

-AND-

* Pt has failed amantadine IR due to frequency of dosing

- OR -

* Dose Change Only: Patient previously met criteria and is already taking the drug

New Member: pt to be transitioned to amantadine IR if above criteria not met

EXHIBIT H

EFFECTIVE
Version
Updated: 04/27/18

Department of Vermont Health Access
Pharmacy Benefit Management Program

Vermont Preferred Drug List and Drugs Requiring Prior Authorization
(includes clinical criteria)

The Commissioner for Office of Vermont Health Access shall establish a pharmacy best practices and cost control program designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall include:

"A preferred list of covered prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives"

From Act 127 passed in 2002

The following pages contain:

- The therapeutic classes of drugs subject to the Preferred Drug List, the drugs within those categories and the criteria required for Prior Authorization (P.A.) of non-preferred drugs in those categories.
- The therapeutic classes of drugs which have clinical criteria for Prior Authorization may or may not be subject to a preferred agent.
- Within bothof these categories there may be drugs or even drug classes that are subject to Quantity Limit Parameters.

Therapeutic class criteria are listed alphabetically. Within each category the Preferred Drugs are noted in the left-hand columns. Representative non-preferred agents have been included and are listed in the right-hand column. Any drug not listed as preferred in any of the included categories requires Prior Authorization.

GHS/Change Healthcare **PRESCRIBER Call Center:** PA Requests Tel: 1-844-679-5363; Fax: 1-844-679-5366 Note: Fax requests are responded to within 24 hrs.	**GHS/Change Healthcare** **PHARMACY Call Center:** PA Requests Tel: 1-844-679-5362 Available for assistance with claims processing	**GHS/Change Healthcare Sr. Account Manager:** Michael Ouellette, RPh Tel: 802-922-9614 Fax: E-Mail: mouellette@changehealthcare.com
	DVHA Pharmacy Unit Staff: Stacey Baker Tel: 802-241-0140 Fax: 802-879-5651 E-Mail: stacey.baker@vermont.gov	**DVHA Pharmacy Administration:** *Director of Pharmacy Services* Nancy Hogue, Pharm. D. Tel: 802-241-0143 Fax: 802-879-5651 E-mail: nancy.hogue@vermont.gov

This is not an all-inclusive list of available covered drugs and includes only managed categories. Unless otherwise stated, the listing of a particular brand or generic name includes all dosage forms of that drug. NR indicates a new drug that has not yet been reviewed by the P&T Committee.

Drugs highlighted in yellow denote a change in PDL status.

To search the PDL, press CTRL + F

PREFERRED AGENTS (No PA required unless otherwise noted)	NON-PREFERRED AGENTS (PA required)	PA CRITERIA
		○Concomitant serum intact parathyroid hormone (PTH) concentrations below the lower limit of the normal laboratory reference range on 2 test dates at least 21 days apart within the past 12 months **AND** ▪ No history of the following: ○mutation in CaSR gene **OR** ○pseudohypoparathyroidism **OR** ○a condition with an increased risk of osteosarcoma **AND** ▪ Hypocalcemia is not corrected by calcium supplements and preferred active forms of vitamin D alone **AND** ▪ Patients must be taking vitamin D metabolite/analog therapy with calcitriol ≥0.25 µg per day OR equivalent **AND** ▪ Must be taking supplemental oral calcium treatment ≥ 1000 mg per day over and above normal dietary calcium intake **AND** ▪ Serum calcium must be ≥ 7.5 mg/dl prior to starting Natpara **AND** ▪ Serum thyroid function tests and serum magnesium levels must be within normal limits **AND** ▪ Documentation of creatinine clearance > 30 mL/min on two separate measurements **OR** creatinine clearance > 60 mL/min AND serum creatinine < 1.5 mg/dL
PARKINSON'S MEDICATIONS		
DOPAMINE PRECURSOR CARBIDOPA/LEVODOPA† (compare to Sinemet®) CARBIDOPA/LEVODOPA† ER (compare to Sinemet® CR) CARBIDOPA/LEVODOPA† ODT **DOPAMINE AGONISTS (ORAL)** BROMOCRIPTINE† (compare to Parlodel®) PRAMIPEXOLE † (compare to Mirapex®) ROPINIROLE† (compare to Requip®)	Rytary® (carbidopa/levodopa ER caps) Sinemet®* (carbidopa/levodopa) Sinemet CR®*(carbidopa/levodopa ER) Mirapex®* (pramipexole) Mirapex ER® (pramipexole ER) *QL = 1 tab/day* Pramipexole ER (compare to Mirapex ER®) Requip®* (ropinirole) Requip XL® (ropinirole XL) *QL = 1 tab/day (all strengths except 12 mg), QL = 2 tabs/day (12 mg)* ropinirole XL† (compare to Requip XL®) *QL = 1 tab/day (all strengths except 12 mg), QL = 2 tabs/day (12 mg)* Tasmar® (tolcapone) Tolcapone (compare to Tasmar®)	**Sinemet, Sinemet CR, Mirapex, Parlodel, Requip:** The patient has had a documented intolerance to the generic product. **Rytary:** The patient has a diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism following intoxication from carbon monoxide or manganese AND the prescriber is a neurologist AND the patient is having breakthrough symptoms despite a combination of concurrent IR and ER formulations of carbidopa/levodopa **Azilect, rasagiline:** The diagnosis or indication is Parkinson's disease. AND The patient has had a documented side effect, allergy, or treatment failure with selegiline. AND The dose requested does not exceed 1 mg/day **carbidopa/levodopa/entacapone**: The patient has had a documented intolerance to brand Stalevo. **Gocovri**: diagnosis or indication is for the treatment of dyskinesia in a patient with Parkinson's Disease AND the patient is currently receiving levodopa-based therapy (with or without concomitant dopaminergic medications) AND the patient has a documented side effect, allergy, or treatment failure with immediate release amantadine. **Note:** treatment failure is defined by a decrease in effectivemess despite attempts to increase dosage to 300mg/day or by temporarily discontinuing amantadine for several weeks and restarting therapy.

PREFERRED AGENTS (No PA required unless otherwise noted)	NON-PREFERRED AGENTS (PA required)	PA CRITERIA
DOPAMINE AGONISTS (TRANSDERMAL) Neupro® (rotigotine) transdermal patch *(Quantity Limit = 1 patch/day)* *(2mg, 4 mg, 6 mg and 8 mg patches)* **COMT INHIBITORS** COMTAN® (entacapone) ENTACAPONE† (compare to Comtan®) **MAO-B INHIBITORS** SELEGILINE† **OTHER** AMANTADINE syrup AMANTADINE† capsules, tablets (PA required for ≤10 day supply) STALEVO® (carbidopa/levodopa/entacapone)	Azilect® (rasagiline) (QL = 1 mg/day) Rasagiline (compare to Azilect®) (QL = 1mg/day) Xadago® (safinamide) (QL=1 tab/day) Zelapar® (selegiline ODT) *(QL = 2.5 mg/day)* carbidopa/levodopa/entacapone† (compare to Stalevo®) Gocovri™ (amantadine extended release) QL = 2 tabs/day)	**Mirapex ER, pramipexole ER, Requip XL, ropinirole XL:** The diagnosis or indication is Parkinson's disease. Requests will not be approved for Restless Leg Syndrome (RLS) AND The patient has had an inadequate response (i.e. wearing off effect or "off" time) with the immediate release product. OR The patient has not been able to be adherent to a three times daily dosing schedule of the immediate release product resulting in a significant clinical impact. AND If the requested product has an AB rated generic, the patient has a documented intolerance to the generic product. **Tasmar, Tolcapone:** The diagnosis or indication is Parkinson's disease. AND The patient has had a documented side effect, allergy, or treatment failure with Comtan or entacapone. For approval of generic talcapone, the patient must have documented intolerance to brand Tasmar. **Xadago:** The diagnosis or indication is Parkinson's disease AND The patient is on current therapy with levodopa/carbidopa AND The patient has had a documented side effect, allergy, or treatment failure with selegiline. Note: Xadago will no be approved for monotherapy. **Zelapar:** The diagnosis or indication is Parkinson's disease. AND The patient is on current therapy with levodopa/carbidopa. AND Medical necessity for disintegrating tablet administration is provided (i.e. inability to swallow tablets or drug interaction with oral selegiline). AND the dose requested does not exceed 2.5mg/day **Limitations:** To prevent the use of amantadine in influenza treatment/prophylaxis, days supply < 10 days will require PA.
PHOSPHODIESTERASE-4 (PDE-4) INHIBITORS		
	Daliresp® tablet (roflumilast) *Quantity limit = 1 tablet/day* Otezla® tablet (apremilast) *(Starter pack – Quantity limit = 27 tablets/14 days)* *(30 mg tablets – Quantity limit = 2 tablets/day)* *** Maximum days' supply per fill = 30)**	**Daliresp:** The indication for the requested medication is treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. AND The patient has had a documented side effect, allergy, treatment failure, or a contraindication to at least one inhaled long-acting anticholinergic AND at least one inhaled long-acting beta-agonist AND at least one inhaled corticosteroid. **Otezla:** The patient has a diagnosis of psoriatic arthritis AND The patient is 18 years of age or older AND The patient has had inadequate response to, intolerance to, or contraindication to methotrexate.