Reference number(s)
385-D

Initial Step Therapy; Post Step Therapy Prior Authorization Urinary Antispasmodics

Generic Step Therapy Plans (GSTP)

Products Referenced by this Document

Brand Name
Gelnique
Gemtesa
Myrbetriq Granules
Oxytrol

Initial Step Therapy

If the patient has filled a prescription for at least a 30 day supply of at least one generic urinary antispasmodic drug within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested branded drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Authorization may be granted for the requested drug when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response after at least a 30 day trial of at least ONE generic urinary antispasmodic drug.
- The patient has a documented contraindication or a potential drug interaction that would prohibit a trial of at least ONE generic urinary antispasmodic drug.

- The patient has experienced an intolerance to at least ONE generic urinary antispasmodic drug.
- The requested drug is being prescribed for the treatment of Neurogenic Detrusor Overactivity (NDO) in a pediatric patient aged 3 years or older and the following criteria is met:
    - The request is for Myrbetriq Granules.

Duration of Approval (DOA)

- 385-D: DOA: 24 months

References

1. Myrbetriq and Myrbetriq Granules [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; April 2021.
2. Oxybutynin Chloride Syrup [package insert]. Philadelphia, PA: Lannett Company, Inc.; February 2020.
3. Oxybutynin Chloride Tablets [package insert]. East Brunswick, NJ: Strides Pharma Inc; November 2021.
4. Oxybutynin Chloride ER Tablets [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; February 2023.
5. Toviaz [package insert]. New York, NY: Pfizer Labs; November 2021. U.S. Food & Drug Administration. FDA News Release: FDA Approves New Indication for Drug to Treat Neurogenic Detrusor Overactivity in Pediatric Patients. March 25, 2021. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-indication-drug-treat-neurogenic-detrusor-overactivity-pediatric-patients. Accessed January 04, 2023.

Document History

Written by: UM Development

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Revised: 09/2009, 10/2009, 07/2010, 08/2010, 05/2011, 10/2011, 01/2012 (added Anturol), 07/2012 (removed Detrol, added Myrbetriq), 09/2012 (updated formatting and documentation), 10/2012 (removed documentation), 12/2012 (removed Sanctura XR), 03/2013 (removed Anturol, updated grids), 04/2013, 01/2014 (removed Detrol LA), 04/2014 (reordered questions & update intolerance question), 10/2014 (removed Myrbetriq from PGST), 04/2015, 01/2016 (removed Enablex), 04/2016 (no clinical changes), 04/2017 (no clinical changes), 04/2018 (removed Toviaz from PGST), 11/2018 (no changes), 01/2019 (removed Vesicare from HPGST & TGST), (SF) 01/2020 (no changes), 01/2021 (no changes); (CJH) 04/2021 (For HPGST and TGST: added Myrbetriq Granules; added questions to allow for approval of Myrbetriq formulations in pediatric patients with NDO), 06/2021 (updated question-set to include new indication for Toviaz); (DFW) 01/2022 (no clinical changes); (CJH) 07/2022 (removed Toviaz from criteria),

(DFW) 11/2022 (Added Gelnique, Myrbetriq, Myrbetriq Granules to PGST targeting); (MRS) 01/2023 (no clinical changes); (KEJ) 01/2024 (no clinical changes); (DFW) 05/2024 (added Gemtesa to HPGST, TGST; removed Myrbetriq tabs); (KEJ) 11/2024 (updated look back to 730 days, retired 375-D and 411-D)

Reviewed: Medical Affairs 05/2009, 09/2009, 10/2009, 07/2010, 08/2010, 10/2011, 01/2012, (KP) 07/2012; (DC) 09/2012, 12/2012, 03/2013, (LS) 04/2013, (KP) 04/2014, (SS) 10/2014, (LB) 04/2015, (CHART) 01/28/2021, 04/22/2021, 07/08/2021, 02/03/2022, 08/04/2022, 12/08/2022, 01/26/2023, 02/01/2024, 06/06/2024, 12/05/2024

External Review: 05/2009, 12/2009, 12/2010, 12/2011, 08/2012, 08/2013, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 04/2019, 04/2020, 06/2021 (FYI), 08/2021 (FYI), 04/2022, 10/2022 (FYI), 04/2023, 09/2024, 12/2024 (FYI)

CRITERIA FOR APPROVAL

1	Has the patient experienced an inadequate treatment response after at least a 30 day trial of at least one generic urinary antispasmodic drug? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Does the patient have a documented contraindication or a potential drug interaction that would prohibit a trial of at least one generic urinary antispasmodic drug? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Has the patient experienced an intolerance to at least one generic urinary antispasmodic drug? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	Is this request for Myrbetriq Granules? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Is the requested drug being prescribed for the treatment of Neurogenic Detrusor Overactivity (NDO) in a pediatric patient aged 3 years or older? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**

1.	Approve, 24 Months	Go to 2	
2.	Approve, 24 Months	Go to 3	
3.	Approve, 24 Months	Go to 4	
4.	Go to 5	Deny	Your plan only covers this drug if you have tried at least one generic urinary antispasmodic drug, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy]
5.	Approve, 24 Months	Deny	Your plan only covers this drug when A) You have tried at least one generic urinary antispasmodic drug, and it did not work well for you, B) You have a medical reason not to take a generic urinary antispasmodic drug, or C) You are using it for Neurogenic Detrusor Overactivity (NDO) in a pediatric patient 3 years old or older. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy - Myrbetriq Granules]