

Market Applicability				
Market	GA	MD	NJ	NY
Applicable	X	X	X	X

Non-Preferred Overactive Bladder Agents Step Therapy

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comments	Quantity Limit
Detrol (tolterodine tartrate) - (brand) Detrol LA (tolterodine tartrate extended-release) - (brand) Ditropan XL (oxybutynin chloride) - (brand) Enablex (darifenacin) - (brand) Gelnique (oxybutynin chloride) Gemtesa (vibegron) Myrbetriq (mirabegron extended-release) tablets Oxytrol Rx Patch (oxybutynin) Toviaz (fesoterodine fumerate extended-release) Vesicare (solifenacin succinate)	Non-Preferred	May be subject to quantity limit
darifenacin extended release oxybutynin tab oxybutynin syrup oxybutynin ER Oxytrol for Women (OTC) patch (oxybutynin) tolterodine, tolterodine ER trospium trospium ER	Preferred	

APPROVAL CRITERIA

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Requests for non-preferred overactive bladder agents may be approved for individuals who meet the following criteria:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to **two** preferred agents;

OR

- II. The preferred agent is not acceptable due to the following concomitant clinical conditions including but not limited to the following:
 - A. Individual is 3 to 17 years of age and the requested agent is Myrbetriq (mirabegron) extended-release tablet;

OR

- III. Gemtesa (vibegron) or Myrbetriq (mirabegron) extended-release tablets are requested, may approve for individuals who meet one of the following:
 - A. Individual with contraindication to antimuscarinic therapy (urinary retention, gastric retention or uncontrolled narrow-angle glaucoma); **OR**
 - B. Individual with dementia at high risk for cognitive impairment with antimuscarinic therapy; **OR**
 - C. Individual who has experienced an adverse event with an antimuscarinic agent.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 7, 2021.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Gormley EA, Lightner DJ, Burgio KL, et. al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guidelines. *J Urol*. 2012; 188: 2455.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Lightner DJ, Gomelsky A, Souter L, et. al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. *J Urol*. 2019; 202: 558.
6. Stein R, Bogaert G, Dogan HS, et.al. EAU/ESPU guidelines on the management of neurogenic bladder in children and adolescent part I diagnostics and conservative treatment. *Neurology Urodynamics*. January 2020; 39(1): 45-57. Available at: <https://onlinelibrary.wiley.com/doi/full/10.1002/nau.24211>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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