| Pharmacy Policy Bulletin: J-1066 Neurogenic Detrusor Overactivity Products – Commercial and Healthcare Reform | |
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| **Number:** J-1066 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.)**:<br>**1.** Other Managed Drugs = Yes w/ Prior Authorization<br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-1066-006 | **Original Date:** 08/05/2020 |
| **Effective Date: 08/23/2024** | **Review Date:** 08/07/2024 |

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| **Drugs Product(s):** | • Myrbetriq (mirabegron extended-release) granules<br>• Vesicare LS (solifenacin succinate) |
| **FDA-Approved Indication(s):** | • Myrbetriq granules<br>o Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older.<br>• Vesicare LS<br>o Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 2 years and older. |

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| **Background:** | • Myrbetriq granules relaxes the detrusor smooth muscle by activation of beta-3 adrenergic receptor (AR), which increase bladder capacity before triggering emptying signals. Vesicare LS is a competitive muscarinic antagonist. Muscarinic receptors play an important role in several major cholinergically mediated functions, including contractions of urinary bladder smooth muscle.<br>• Overactive bladder (OAB) is characterized by urgency, with or without incontinence, usually associated with frequency and nocturia. When a condition is the result of urodynamically demonstrable involuntary bladder contractions, it is called NDO. NDO is characterized by overactivity of the bladder wall muscle, resulting in sporadic bladder muscle contraction that increases pressure in the bladder and decreases the volume of urine it can hold. Symptoms include urinary frequency, urgency, and/or incontinence. NDO is frequently observed in patients with neurological conditions including spina bifida, multiple sclerosis (MS), and spinal cord injury (SCI). It can lead to unexpected and frequent leakage of urine. With early treatment, the upper urinary tract is preserved in up to 90% of patients.<br>• According to the European Association of Urology (EASU) Guidelines on the Management of Neurogenic Bladder in Children and Adolescents, detrusor overactivity causes a high-pressure bladder, which is dangerous for the upper urinary tract. Antimuscarinic and anticholinergic medications reduce and/or prevent detrusor overactivity and lower intravesical pressure.<br>• According to the National Institute for Health and Care Excellence Guidelines for Urinary Incontinence in Neurological Disease, antimuscarinics are recommended |

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| | for NDO. There is no high quality evidence to differentiate between the antimuscarinic agents. Cost and side effect profile should be considered when choosing the appropriate agent.<br>• Early treatment with anticholinergics has been shown to lower the rate of renal deterioration as well as the need for bladder augmentation. Therefore, anticholinergic treatment should be started if an overactive bladder is demonstrated on urodynamic studies, even within the first months of life. NDO impacts a young population, as such cognitive impairment seen with oxybutynin appear to be less frequent in pediatrics than elderly adults.<br>• Prescribing considerations:<br>o Myrbetriq Granules<br>▪ Myrbetriq granules does not have the additional indication for OAB in adults.<br>▪ Myrbetriq and Myrbetriq granules are not substitutable on a milligram-per-milligram basis. A recommended dosage for Myrbetriq granules for adults has not been established.<br>▪ Increases in blood pressure is a known side effect in adults taking Myrbetriq and was also seen in pediatric patients taking Myrbetriq granules for NDO.<br>o Vesicare LS<br>▪ Promptly discontinue Vesicare LS and provide appropriate therapy if angioedema or anaphylaxis.<br>▪ Vesicare LS is not recommended in patients with clinically significant bladder outlet obstruction in the absence of clean intermittent catheterization, with decreased gastrointestinal motility or in patients with high risk of QT prolongation, including a known history or on concurrent medications known to prolong the QT interval. |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Myrbetriq granules or Vesicare LS may be approved when all of the following criteria are met **(A., B., and C.)**:

**A.** The member meets one (1) of the following criteria **(1. or 2.)**:
  **1.** If the request is for Vesicare LS, the member is 2 to 17 years of age.
  **2.** If the request is for Myrbetriq granules, the member is 3 to 17 years of age.

**B.** The member has a diagnosis of neurogenic detrusor overactivity (No ICD-10 Code).

**C.** If the member is 6 years of age or older, the member has experienced therapeutic failure, contraindication, or intolerance to generic oxybutynin or generic oxybutynin ER.

**II. Reauthorization**

When a benefit, reauthorization of Myrbetriq granules or Vesicare LS may be approved when the following criterion is met **(A.)**:

**A.** The prescriber attests that the member has experienced positive clinical response to therapy.

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Myrbetriq [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; March 2021.
2. Vesicare LS [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; May 2020.
3. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024. Accessed June 12, 2024.
4. Stein R, Bogaert G, Dogan HS. EAU/ESPU guidelines on the management of neurogenic bladder in children and adolescents part I diagnostics and conservative treatment. *Neurourol*. *Urodyn*. 2020; 39(1):45-57.
5. EAU Guidelines. Edn. presented at the EAU Annual Congress Paris 2024. ISBN 978-94-92671-23-3.
6. National Institute for Health and Care Excellence (NICE). Urinary incontinence in neurological disease: Assessment and management (CG148). [PDF]. NICE Guidance, https://www.nice.org.uk/guidance/cg148/resources/urinary-incontinence-in-neurological-disease-assessment-and-management-pdf-35109577553605. Accessed June 12, 2024.