

Myrbetriq (mirabegron)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Myrbetriq (mirabegron) is a beta-3 adrenergic receptor (beta-3 AR) agonist indicated for the treatment of adults with overactive bladder (OAB) with symptoms of urge urinary incontinence, including urinary urgency and frequency. Myrbetriq (mirabegron) can be prescribed either as monotherapy or as combination therapy with solifenacin, a bladder-specific antimuscarinic agent. It is also indicated for neurogenic detrusor overactivity (NDO) in pediatric individuals 3 years and older. By relaxing the detrusor muscle via beta-3 AR activation, bladder capacity is increased during the urine storage phase.

Beta-3 ARs are usually well-tolerated by most and offer an alternative for those experiencing intolerance to selective bladder anticholinergic antimuscarinics. Per guidelines for non-neurogenic OAB, either bladder-specific antimuscarinics or beta-3 ARs may be used as a second-line to behavioral interventions. Clinicians may consider combination therapy with an anticholinergic antimuscarinic agent and beta-3 AR for those refractory to monotherapy with either an anticholinergic antimuscarinic or beta-3 AR alone.

Mirabegron therapy has the potential for increasing blood pressure and use is not recommended for those patients with severe uncontrolled hypertension (Adults, systolic blood pressure (SBP) ≥ 180 mmHg or diastolic blood pressure (DBP) ≥ 110 mmHg; Pediatrics, SBP and/or DBP above the 99th percentile plus 5 mmHg for age, sex, and stature).

Definitions

"Neurogenic Detrusor Overactivity (NDO)" is detrusor overactivity due to a neurologic condition, such as spinal cord injury or multiple sclerosis, resulting in urinary urgency, frequency, and incontinence.

"Overactive Bladder (OAB)" is a symptom complex characterized by urinary urgency, usually accompanied by increased urinary frequency and nocturia, with or without urge urinary incontinence.

"Urinary antispasmodics" are FDA-approved medications used to treat overactive bladder, urinary urgency, and urge incontinence.

"Urinary retention" is the incomplete emptying of the bladder.

Clinical Indications

The Plan considers Myrbetriq (mirabegron) medically necessary when ALL the following criteria are met for the applicable indication listed below:

Medical Necessity Criteria for Initial Authorization

Adult Overactive Bladder (OAB)

1. The member is 18 years of age or older; *AND*
2. The member has a diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; *AND*
3. The member has documented trial and failure of behavioral therapies (e.g., bladder training, pelvic floor muscle training, fluid management); *AND*
4. The member is unable to use, or has tried and failed TWO (2) of the following for at least a 30 day duration each:
 - a. Darifenacin; *and/or*
 - b. Fesoterodine; *and/or*
 - c. Oxybutynin; *and/or*
 - d. Solifenacin; *and/or*
 - e. Tolterodine; *and/or*
 - f. Trospium; *AND*
5. The member does NOT have ANY of the following:
 - a. End stage renal disease (defined as an estimated glomerular filtration rate [eGFR] <15 mL/min/1.73m²); *or*
 - b. Uncontrolled hypertension defined as systolic blood pressure ≥ 180mm Hg and/or diastolic blood pressure ≥ 110mm Hg; *AND*

6. Myrbetriq (mirabegron) is prescribed at FDA-approved dosing for overactive bladder of 25-50 mg once daily.

Pediatric Neurogenic Detrusor Overactivity (NDO)

1. The member is 3 years of age or older; *AND*
2. The member has a diagnosis of neurogenic detrusor overactivity; *AND*
3. The member has documented trial and failure of non-pharmacologic therapies (e.g. voiding behavior modification); *AND*
4. IF the member is 6 years of age or older, the member is unable to use, or has tried and failed BOTH of the following for at least a 30 day duration each:
 - a. fesoterodine; *and/or*
 - b. oxybutynin; *AND*
5. The member does NOT have ANY of the following:
 - a. Severe uncontrolled hypertension, defined as a systolic and/or diastolic blood pressure above the 99th percentile plus 5 mm Hg for age, sex, and stature using appropriate reference values; *or*
 - b. End stage renal disease (eGFR <15 mL/min/1.73m²); *AND*
6. Myrbetriq (mirabegron) is prescribed at FDA-approved weight-based dosing for pediatric NDO:
 - a. 11 kg to <22 kg: Oral granules 24-48 mg once daily; *or*
 - b. 22 kg to <35 kg: Oral granules 32-64 mg once daily; *or*
 - c. IF the member is ≥35 kg, ONE (1) of the following:
 - i. Oral tablets 25-50 mg once daily; *or*
 - ii. IF the member is unable to swallow, oral granules 48-80 mg once daily.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Medical Necessity Criteria for Reauthorization

Adult Overactive Bladder (OAB)

Reauthorization for overactive bladder in adults will be granted for up to 12 months if the member has experienced clinically significant improvement in urgency, frequency and incontinence episodes documented in chart notes.

Pediatric Neurogenic Detrusor Overactivity (NDO)

Reauthorization for pediatric neurogenic detrusor overactivity will be granted for up to 12 months if the member has a documented positive clinical response such as reduced incontinence episodes or improved bladder capacity.

Experimental or Investigational / Not Medically Necessary

Myrbetriq (mirabegron) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Kidney Stones.
- Interstitial Cystitis.
- Multiple Sclerosis.
- Nocturnal Enuresis.
- Parkinson's Disease (PD).

References

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Clinical Guideline Revision / History Information

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