Clinical Guideline

Oscar Clinical Guideline: Myrbetriq (mirabegron) (PG181, Ver. 2)

# 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 adult patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency, 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 patients 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 patients and offer an alternative for patients experiencing intolerance to selective bladder 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 antimuscarinic and beta-3 AR for patients refractory to monotherapy with either an 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 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** 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 (eGFR <15 mL/min/1.73m$^2$); ***or***
    b. Uncontrolled hypertension defined as systolic blood pressure ≥ 180mm Hg and/or diastolic blood pressure ≥ 110mm Hg; ***AND***
6. Mirabegron is prescribed at FDA-approved dosing for overactive bladder of 25-50 mg once daily.

<u>Pediatric Neurogenic Detrusor Overactivity (NDO)</u>

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/1.73m$^2$); ***AND***
6. 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. ≥35 kg: Oral tablets 25-50 mg once daily or oral granules 48-80 mg once daily.

<u>**If the above prior authorization criteria are met, the requested product will be authorized for 12-months.**</u>

## Medical Necessity Criteria for Reauthorization

### Adult Overactive Bladder (OAB)

Reauthorization for overactive bladder in adults will be granted for 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 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


1. Cameron AP, Chung DE, Dielubanza EJ, Enemchukwu E, Ginsberg DA, Helfand BT, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. Journal of Urology [Internet]. 2024 Jul 1 [cited 2024 Nov 19];212(1):11–20. Available from: https://doi.org/10.1097/JU.0000000000003985
2. Chen HL, Chen TC, Chang HM, et al. Mirabegron is alternative to antimuscarinic agents for overactive bladder without higher risk in hypertension: a systematic review and meta-analysis. World J Urol. 2018;36(8):1285-1297. doi:10.1007/s00345-018-2268-9
3. Johnson EK, Bauer SB: Neurogenic voiding dysfunction and functional voiding disorders: Evaluation and nonsurgical management. In The Kelalis-King-Belman Textbook of Clinical Pediatric Urology, ed. 6, edited by Docimo S, Canning D, Khoury A, Salle JLP. Boca Raton, CRC Press, 2019, pp. 820–852.
4. Kobashi KC, Albo ME, Dmochowski RR, et al: Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. J Urol 198(4):875-883, 2017. doi: 10.1016/j.juro.2017.06.061
5. Lerner LB, McVary KT, Barry MJ, Bixler BR, Dahm P, Das AK, Gandhi MC, Kaplan SA, Kohler TS, Martin L, Parsons JK, Roehrborn CG, Stoffel JT, Welliver C, Wilt TJ. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I-

Initial Work-up and Medical Management. J Urol. 2021 Oct;206(4):806-817. doi: 10.1097/JU.0000000000002183. Epub 2021 Aug 13. Erratum in: J Urol. 2021 Nov;206(5):1339. doi: 10.1097/JU.0000000000002231. PMID: 34384237.
6. Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. Journal of Urology [Internet]. 2019 Sep 1 [cited 2024 Nov 19];202(3):558–63. Available from: https://doi.org/10.1097/JU.0000000000000309
7. Myrbetriq (mirabegron) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; April 2021.
8. O'Mahony D, Cherubini A, Guiteras AR, Denkinger M, Beuscart JB, Onder G, Gudmundsson A, Cruz-Jentoft AJ, Knol W, Bahat G, van der Velde N, Petrovic M, Curtin D. STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. Eur Geriatr Med. 2023 Aug;14(4):625-632. doi: 10.1007/s41999-023-00777-y. Epub 2023 May 31. Erratum in: Eur Geriatr Med. 2023 Aug;14(4):633. doi: 10.1007/s41999-023-00812-y. PMID: 37256475; PMCID: PMC10447584.
9. Staskin D, Frankel J, Varano S, et al: International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: EMPOWUR. J Urol 204(2):316-324, 2020. doi: 10.1097/JU.0000000000000807

## Clinical Guideline Revision / History Information

| |
|---|
| Original Date: 11/29/2023 |
| Reviewed/Revised: 12/02/2024 |