AFTNA BF	TTER HEALTH®		<b>*</b> ae	etna <sup>®</sup>		
Coverage Policy/Guideline						
Name:	Mirabegron		Page:	1 of 2		
Effective Date: 8/4/2025			Last Review Date:	5/2025		
Applica	□Illinois	□Florida	□Michigan			
Applies to:	⊠New Jersey	⊠Maryland	⊠Florida Kids			
	⊠Pennsylvania Kids	□Virginia	☐Kentucky PRMD			

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for mirabegron under the patient's prescription drug benefit.

# **Description:**

#### **FDA-approved Indications**

- Mirabegron ER tablets are indicated for the treatment of overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency.
- 2. Mirabegron ER tablets, in combination with the muscarinic antagonist solifenacin succinate, are indicated for the treatment of OAB in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency.
- 3. Mirabegron Granules are indicated for the treatment of Neurogenic Detrusor Overactivity (NDO) in pediatric patients aged 3 years and older.
- 4. Mirabegron ER tablets are indicated for the treatment of NDO in pediatric patients aged 3 years and older and weighing 35 kg or more.

### **Applicable Drug List:**

Mirabegron ER Tablets

#### **Initial Step Therapy**

If the patient has filled a prescription for at least a 30-day supply of an antimuscarinic (e.g., fesoterodine, oxybutynin, solifenacin, tolterodine, or trospium) within the past 130 days under this prescription benefit, then mirabegron will be paid. If the patient does not meet the initial screen out logic criteria, then the claim will reject indicating that a prior authorization (PA) is required. This PA criteria would then be applied to requests submitted for evaluation to the PA unit.

# **Coverage Criteria**

Authorization may be granted when prescribed for the treatment of OAB or NDO when ONE of the following criteria are met:

 The patient has experienced an inadequate treatment response to a maximally titrated dose of an antimuscarinic (e.g., fesoterodine, oxybutynin, solifenacin, tolterodine, or trospium)

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- The patient has experienced an intolerance to a formulary preferred antimuscarinic (e.g., fesoterodine, oxybutynin, solifenacin, tolterodine, or trospium)
- Treatment with antimuscarinics (e.g., fesoterodine, oxybutynin, solifenacin, tolterodine, and trospium) is contraindicated or inadvisable for the patient

# **Continuation of Therapy**

Authorization may be granted if the patient has achieved or maintained a positive clinical response since beginning treatment.

## **Approval Duration and Quantity Restrictions:**

**Initial and Renewal Approval: 12 months** 

Quantity limit: 30 tablets every 30 days

#### **References:**

- 1. Myrbetriq [package insert]. Northbrook, IL: Astellas Pharma US, Inc.; August 2024.
- 2. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. J Urol. Published online April 23, 2024. doi:10.1097/JU.000000000003985.
- 3. Nepple KG, Cooper CS. Management of bladder dysfunction in children. In: UpToDate, Baskin LS, Matoo TK (Ed), Wolters Kluwer. (Accessed on May 1, 2025.)
- 4. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier. c2025- [cited 2025 May 1]. Available from: http://www.clinicalkey.com.