AdvancedHealth
Bridging the Future of Healthcare

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Myrbetriq Drug Use Criteria

Created: 1/8/2024
Reviewed:

Includes:

Brand©	*Generic*
Myrbetriq©	*Mirabegron*

GUIDELINE FOR USE:

Initial Request:

1. Is the medication being used to treat a funded condition for coverage by Oregon Health Plan?
    a. If yes, go to #3.
    b. If no, go to #2.
2. Does member have a comorbid condition that would allow coverage?
    a. If yes, go to #3.
    b. If no, deny as below the line. The Oregon Health Plan does not pay for treatment of this condition.
3. Has the member used at least 2 least costly alternatives (oxybutynin IR, oxybutynin ER, and solifenacin are on formulary without a prior authorization; tolterodine IR, tolterodine ER, darifenacin, trospium, and fesoterodine are on formulary as step therapy after trial of oxybutynin or solifenacin) Does fill history support trial or is there documentation from previous trials?
    a. If yes, approve for up to 12 months.
    b. If no, go to #4.
4. Did the provider give clinical rationale to why 2 least costly alternatives could not be used?
    a. If yes, approve for up to 12 months.
    b. If no, deny as criteria not met. Please trial at least 2 least costly alternatives (oxybutynin IR, oxybutynin ER, and solifenacin are on formulary without a prior authorization; tolterodine IR, tolterodine ER, darifenacin, trospium, and fesoterodine are on formulary as step therapy after trial of oxybutynin or solifenacin).

Renewal Request:

1. Does fill history support adherence and a positive response to therapy? (Adherence is defined as Medication Possession Ratio (MPR) greater than or equal to 80% or no gaps between fills that exceed 5 days).
    a. If yes, approve for up to 12 months.
    b. If no, go to #2.
2. Does prescriber provide clinical rationale as to why member was not adherent to medication or why the member should continue the medication without a positive response?
    a. If yes, approve for up to 12 months.

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b. If no, deny as not meeting criteria. Please change to another medication or provide documentation of counseling on importance of adherence to medication.

Rationale:
To promote cost-effective treatment of covered OHP conditions.

FDA Approved Indications:
MYRBETRIQ is a beta-3 adrenergic agonist indicated for the treatment of:

- Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate.
- Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more.

MYRBETRIQ Granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients aged 3 years and older

Mechanism of Action:
Mirabegron, a beta-3 adrenergic receptor agonist, activates beta-3 adrenergic receptors in the bladder resulting in relaxation of the detrusor smooth muscle during the urine storage phase, thus increasing bladder capacity. At usual doses, mirabegron is believed to display selectivity for the beta-3 adrenergic receptor subtype compared to its affinity for the beta-1 and -2 adrenoceptor subtypes. Data have shown that beta-adrenoceptors, predominately the beta-3 subtype, mediate detrusor smooth muscle tone and promote the storage function of the human bladder.

Dosing:

- Adults
  - Initial: 25 mg once daily. May increase to 50 mg once daily after 4 to 8 weeks based on response and tolerability.
- Pediatrics
  - 11 to <22 kg: Oral: Granules: Initial: 24 mg once daily; after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 48 mg/day once daily.
  - 22 to <35 kg: Oral: Granules: Initial: 32 mg once daily; after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 64 mg/day once daily.
  - ≥35 kg: Oral:
    - Granules: Initial: 48 mg once daily; after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 80 mg/day once daily.
    - Tablets: Initial: 25 mg once daily; after 4 to 8 weeks of therapy, may increase dose if needed up to a maximum daily dose: 50 mg/day once daily.

Contraindications:

- Hypersensitivity to mirabegron or any component of the formulation

Dose Adjustments:

- Renal Impairment
  - Adults
    - eGFR ≥ 30mL/minutes/1.73m^2= no dosage adjustment

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- eGFR 15 to <30mL/minutes/1.73m^2= do not exceed 25mg once daily
- eGFR < 15mL/minutes/1.73m^2= Not recommended

- Pediatrics
  - eGFR 30 to 89mL/minutes/1.73m^2= no dosage adjustment
  - eGFR 15 to 29mL/minutes/1.73m^2
    - 11 to <22 kg: granules: do not exceed 24mg once daily
    - 22 to <35kg: granules: do not exceed 32mg once daily
    - ≥35kg:
      - Granules: do not exceed 48mg once daily
      - Tablets: do not exceed 25mg once daily
  - eGFR <15mL/minutes/1.73m^2= not recommended

References:

- Mirabegron Drug Information. UpToDate. Accessed January 8, 2024.
- Myrbetriq prescribing information. Revised 4/2021. https://www.astellas.com/us/system/files/Myrbetriq_WPI.pdf