Oscar Clinical Guideline: fesoterodine (Toviaz) (PG102, Ver. 5)

fesoterodine (Toviaz)

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

Fesoterodine (Toviaz) is an anticholinergic medication used as a urinary antispasmodic agent. It antagonizes acetylcholine at muscarinic cholinergic receptors, relaxing bladder smooth muscle, decreasing detrusor pressure, and reducing bladder contractions. Fesoterodine is often used in treating overactive bladder (OAB), urinary incontinence, and urinary urgency. Initial treatments for these conditions usually include lifestyle modifications, pelvic floor exercises in women, bladder training, and management of urinary symptom-causing factors. If non-drug treatments fail to provide sufficient symptom improvement, urinary antispasmodic agents like fesoterodine may be employed. It takes up to 12 weeks for these medications to demonstrate effectiveness.

Fesoterodine is FDA-approved for treating OAB in adults and neurogenic detrusor overactivity (NDO) in pediatric patients aged 6 and above who weigh 25 kilograms or more. The drug is available as extended-release tablets, which can help reduce side effect occurrence.

Table 1: fesoterodine (Toviaz) Dosage Information

Indication	Initial dose	Subsequent dose	Additional Considerations
Overactive Bladder -or- Neurogenic Detrusor Overactivity	4 mg PO qd	May increase to 8 mg PO qd based on response and tolerability.	Dose not to exceed 4 mg/day if the patient is taking concomitant potent CYP3A4 inhibitors.

Definitions

"**Anticholinergic**" medications block acetylcholine, a natural chemical, reducing bladder spasms.

"**Neurogenic detrusor overactivity (NDO)**" involves involuntary detrusor muscle contractions due to nerve damage often caused by illnesses or injuries.

"**Overactive bladder (OAB)**" is a syndrome characterized by sudden, uncontrollable urges to urinate, often with increased frequency and nocturnal occurrence. It may lead to 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.

Medical Necessity Criteria for Initial Authorization

The Plan considers **fesoterodine (Toviaz)** medically necessary when **ALL** of the following criteria are met for the applicable indication listed below:

For the treatment of overactive bladder (OAB)

1. The member is 18 years or older; ***AND***
2. The member has a documented diagnosis of overactive bladder (OAB) with symptoms of urinary incontinence, urgency, and frequency; ***AND***
3. The member is unable to use, or has tried and failed at least THREE (3) of the following formulary extended-release alternatives for at least a 30 day duration each:
    a. darifenacin ER; ***and/or***
    b. oxybutynin ER; ***and/or***
    c. tolterodine ER; ***and/or***
    d. trospium ER; ***AND***

4. Chart documentation is provided for review to validate the above-listed requirements.

For the treatment of neurogenic detrusor overactivity (NDO)

1. The member is 6 years or older; ***AND***
2. The member weighs more than 25 kilograms (55 pounds); ***AND***
3. The member has a documented diagnosis of neurogenic detrusor overactivity (NDO) with symptoms of urinary incontinence, urgency, and frequency; ***AND***
4. The member is unable to use, or has tried and failed oxybutynin at the maximum tolerated dose for at least a 30-day duration; ***AND***
5. Chart documentation is provided for review to validate the above-listed requirements.

If the member meets the criteria listed above, fesoterodine (Toviaz) will be approved for 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member's chart documentation demonstrates clinical symptom improvement since beginning fesoterodine (Toviaz) treatment.

Experimental or Investigational / Not Medically Necessary

fesoterodine (Toviaz) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

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