Oscar Clinical Guideline: fesoterodine (Toviaz) (PG102, Ver. 6)

fesoterodine (Toviaz)

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 (Toviaz) 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, bladder training, and management of urinary symptom-causing factors. If non-drug treatments fail to provide sufficient symptom improvement, urinary antispasmodic agents like fesoterodine (Toviaz) may be employed. It takes up to 12 weeks for these medications to demonstrate effectiveness.

Fesoterodine is FDA-approved for treating OAB in adults with symptoms of urinary incontinence,urgency and frequent; and, neurogenic detrusor overactivity (NDO) in pediatrics 6 years of age and older (and weighing 25 kilograms [kg] 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 daily	May increase to 8 mg PO daily based on response and tolerability.	Dose not to exceed 4 mg/day in adults and pediatrics weighing 35 kg or more taking concomitant strong CYP3A4 inhibitors. Use is not recommended in pediatrics weighing 25 to 35 kg and taking concomitant strong CYP3A4 inhibitors. Dosing should not exceed 4 mg daily in those with CrCl <30 ml/min. Use is not recommended in pediatrics (weighing 25 to 35 kg) with an eGFR <30 ml/min/1.73m^2. Use is not recommended in pediatrics (weighing more than 35 kg) with an eGFR <15 ml/min/1.73m^2 or requiring dialysis.
PO, per os (by mouth); CrCl, creatinine clearance (a measure of kidney function); eGFR, estimate glomerular filtration rate (a measure of kidney function) *Strong CYP3A4 inhibitors examples include: ketoconazole, itraconazole, clarithromycin*			

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/or 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 (Enablex); *and/or*
    b. Oxybutynin ER (Ditropan); *and/or*
    c. Solifenacin succinate (Vesicare); *and/or*
    d. Tolterodine ER (Detrol LA); *and/or*
    e. Trospium ER (Sancura XR); *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/or frequency; *AND*
4. The member is unable to use, or has tried and failed oxybutynin (Ditropan) 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 up to 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 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.

References

1. 2019 surveillance of urinary incontinence in neurological disease: assessment and management (NICE guideline CG148) [Internet]. London: National Institute for Health and Care Excellence (NICE); 2019 Jan 31.
2. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. 2015 Nov;126(5):e66-e81. doi: 10.1097/AOG.0000000000001148. PMID: 26488524.
3. Baboudjian M, Hashim H, Bhatt N, et al. Summary Paper on Underactive Bladder from the European Association of Urology Guidelines on Non-neurogenic Male Lower Urinary Tract Symptoms. Eur Urol. 2024 Sep;86(3):213-220. doi: 10.1016/j.eururo.2024.04.004. Epub 2024 Apr 21.
4. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. Neurourol Urodyn. 2024 Nov;43(8):1742-1752. doi: 10.1002/nau.25532. Epub 2024 Jul 15.
5. Clinical Consensus Statement: Association of Anticholinergic Medication Use and Cognition in Women With Overactive Bladder. Female Pelvic Med Reconstr Surg. 2021 Feb 1;27(2):69-71. doi: 10.1097/SPV.0000000000001008.
6. Ginsberg DA, Boone TB, Cameron AP et al: The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up. J Urol 2021; 206: 1106.
7. 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.
8. Madhuvrata P, Cody JD, Ellis G, et al. Which anticholinergic drug for overactive bladder symptoms in adults. Cochrane Database Syst Rev. 2012;1:CD005429.
9. McVary KT, Roehrborn CG, Avins AL, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. J Urol. 2011;185(5):1793.
10. Micromedex (electronic version). IBM Watson Health, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed Sept 2021.
11. Nambiar AK, Arlandis S, Bø K, et al. European Association of Urology Guidelines on the Diagnosis and Management of Female Non-neurogenic Lower Urinary Tract Symptoms. Part 1: Diagnostics, Overactive Bladder, Stress Urinary Incontinence, and Mixed Urinary Incontinence. Eur Urol. 2022 Jul;82(1):49-59. doi: 10.1016/j.eururo.2022.01.045. Epub 2022 Feb 23.
12. O'Mahony, D., Cherubini, A., Guiteras, A.R. et al. Correction: STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. Eur Geriatr Med 14, 633 (2023). https://doi-org.libproxy.unm.edu/10.1007/s41999-023-00812-y
13. Qaseem A, Dallas P, Forciea MA, et al. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014;161(6):429.
14. Russo E, Caretto M, Giannini A, et al. Management of urinary incontinence in postmenopausal women: An EMAS clinical guide. Maturitas. 2021 Jan;143:223-230. doi: 10.1016/j.maturitas.2020.09.005. Epub 2020 Sep 30.
15. Toviaz (fesoterodine) [prescribing information]. New York, NY: Pfizer Inc; February 2024.
16. U.S. Food & Drug Administration. FDA News Release: FDA Approves New Indication for Drug to Treat Neurogenic Detrusor Overactivity in Pediatric Patients. March 25, 2021. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-indication-drug-treat-neurogenic-detrusor-overactivity-pediatric-patients. Accessed Sept 2021.

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