



Prior Authorization Approval Criteria

Toviaz (fesoterodine fumarate)

Generic name:	Fesoterodine fumarate
Brand name:	Toviaz
Medication class:	Urinary antispasmodic/Antimuscarinic
FDA-approved uses:	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
Available dosage forms:	4 mg and 8 mg extended-release tablet
Usual dose:	4 mg orally once daily, may increase to 8 mg once daily
Approximate monthly cost: (based on AWP 2009)	\$143.10 per month for both 4 mg and 8 mg tablets.
Duration of therapy:	Indefinite

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Patient has a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency
- Patient has tried and failed at least 2 other antimuscarinic agents.

Caution:

- Bladder outflow obstruction
- Decreased gastrointestinal motility
- Myasthenia gravis
- Severe renal impairment
- Severe hepatic impairment

Monitoring: Symptomatic improvement

Contraindication:

- Gastric retention
- Uncontrolled narrow-angle glaucoma
- Urinary retention
- Hypersensitivity to fesoterodine fumarate or any other component of the product

Special considerations:

- Fesoterodine fumarate is a prodrug, which is rapidly and extensively converted by non-specific esterases to its active metabolite, 5-hydroxymethyl tolterodine (5-HMT), which is also the active metabolite of tolterodine
- Fesoterodine fumarate 4 mg and 8 mg has been compared in head-to-head clinical trials with tolterodine ER 4 mg without any significant clinical improvement
- Fesoterodine fumarate 4 mg and 8 mg has been compared to solifenacin using data from the published literature showing no significant clinical improvement

FDA approved medications for the treatment of overactive bladder (OAB)			
Drug name	Cost/month	Tier	Generic availability
Darifenacin (Enablex) (7.5-, 15- mg ER tabs)	\$99.60*	3	No
Oxybutynin chloride – Average generic price (5-, mg IR tabs, syrup)	\$22.80*	1	Yes
Ditropan (5mg tabs)	\$64.20*	3	
Ditropan XL (5-, 10-, 15- mg ER tabs)	\$94.20*	3	
Oxytrol (transdermal patch)	\$88.16*	3	
Solifenacin (Vesicare) (5-, 10- mg tabs)	\$100.20*	3	No
Tolterodine tartrate Detrol (1-, 2- mg IR Tabs)	\$105.60*	3	No
Detrol LA (2-, 4- mg ER caps)	\$91.80*	3	
Trospium chloride Sanctura (20- mg tabs)	\$82.20*	3	No
Fesoterodine fumarate Toviaz (4-, 8- mg ER tabs)	\$143.10 (current price)	3 PA	No

* Cost of monthly treatment according to "The Medical Letter" for January 1, 2005

Not approved if:

- Patient has any contraindications to the use of Toviaz
- Patient does not meet the above-stated criteria

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/10/09