



# Urinary Incontinence Quantity Limit Program Summary

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

## POLICY REVIEW CYCLE

**Effective Date**  
07-01-2024

**Date of Origin**  
10-01-2008

## FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Detrol LA® (tolterodine) Capsule*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	*generic equivalent available	1
Detrol® (tolterodine) Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	*generic equivalent available	2
Ditropan XL® (oxybutynin) Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency  Treatment of pediatric patients aged 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida)	*generic equivalent available	3
Enablex® (darifenacin) Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency	*generic equivalent available	4
Gelnique® (oxybutynin) Gel	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency		5
Gemtesa® (vibegron) Tablet	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults		6
Myrbetriq® (mirabegron)	Tablets:	*generic available	7

Agent(s)	FDA Indication(s)	Notes	Ref#
Tablet* Granules for suspension	Treatment as monotherapy or in combination with solifenacin for overactive bladder in adult patients with symptoms of urge urinary incontinence, urgency, and frequency  Treatment of neurogenic detrusor overactivity in pediatric patients aged 3 years and older and weighing 35 kg or more  Granules:  Treatment of neurogenic detrusor overactivity in pediatric patients aged 3 years and older		
oxybutynin Solution*	Relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria)	*generic equivalent available	21
oxybutynin Syrup	Relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria)		8
oxybutynin Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults  Treatment of pediatric patients aged 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida)	*generic equivalent available	9
Oxytrol® [RX], Oxytrol for Women® [OTC]  (oxybutynin)  Transdermal patch	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency		10 ; 11
Toviaz®  (fesoterodine)  Tablet*	Treatment of overactive bladder in adults with symptoms of urge urinary incontinence, urgency, and frequency  Treatment of neurogenic detrusor overactivity in pediatric patients 6 years of age and older with a body weight greater than 25 kg	*generic equivalent available	12
tropium ER Capsule*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	*generic equivalent available	13
tropium Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	*generic equivalent available	14
Vesicare LS®  (solifenacin)	Treatment of adults with neurogenic detrusor overactivity (NDO) in pediatric patients aged 2 years and older		16

Agent(s)	FDA Indication(s)	Notes	Ref#
Suspension			
Vesicare® (solifenacin)  Tablet*	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	*generic equivalent available	15

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

### POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	darifenacin hydrobromide tab er	15 MG ; 7.5 MG	30	Tablets	30	DAYS			
	oxybutynin chloride solution	5 MG/5ML	600	mLs	30	DAYS			
	oxybutynin chloride tab	2.5 MG	90	Tablets	30	DAYS			
	Oxybutynin Chloride Tab 5 MG	5 MG	120	Tablets	30	DAYS			
	Oxybutynin Chloride Tab ER 24HR 15 MG	15 MG	60	Tablets	30	DAYS			
	tropium chloride cap er	60 MG	30	Capsules	30	DAYS			
	tropium chloride tab	20 MG	60	Tablets	30	DAYS			
Detrol	tolterodine tartrate tab	1 MG ; 2 MG	60	Tablets	30	DAYS			
Detrol la	tolterodine tartrate cap er	2 MG ; 4 MG	30	Capsules	30	DAYS			
Ditropan xl	Oxybutynin Chloride Tab ER 24HR 10 MG	10 MG	60	Tablets	30	DAYS			
Ditropan xl	Oxybutynin Chloride Tab ER 24HR 5 MG	5 MG	30	Tablets	30	DAYS			
Gelnique	oxybutynin chloride td gel	10 %	30	Sachets	30	DAYS			
Gemtesa	vibegron tab	75 MG	30	Tablets	30	DAYS			
Myrbetriq	mirabegron granules for oral extended release susp	8 MG/ML	300	mLs	28	DAYS			
Myrbetriq	mirabegron tab er	25 ; 25 MG ; 50 ; 50 MG	30	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Oxytrol ; Oxytrol for women	oxybutynin td patch twice weekly	3.9 MG/24HR	8	Patches	28	DAYS			
Toviaz	fesoterodine fumarate tab er	4 MG ; 8 MG	30	Tablets	30	DAYS			
Vesicare	solifenacin succinate tab	10 MG ; 5 MG	30	Tablets	30	DAYS			
Vesicare ls	solifenacin succinate susp	5 MG/5ML	300	mLs	30	DAYS			

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	darifenacin hydrobromide tab er	15 MG ; 7.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	oxybutynin chloride solution	5 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	oxybutynin chloride tab	2.5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Oxybutynin Chloride Tab 5 MG	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Oxybutynin Chloride Tab ER 24HR 15 MG	15 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	tropium chloride cap er	60 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	tropium chloride tab	20 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Detrol	tolterodine tartrate tab	1 MG ; 2 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Detrol la	tolterodine tartrate cap er	2 MG ; 4 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ditropan xl	Oxybutynin Chloride Tab ER 24HR 10 MG	10 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Ditropan xl	Oxybutynin Chloride Tab ER 24HR 5 MG	5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Gelnique	oxybutynin chloride td gel	10 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Gemtesa	vibegron tab	75 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Myrbetriq	mirabegron granules for oral extended release susp	8 MG/ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Myrbetriq	mirabegron tab er	25 ; 25 MG ; 50 ; 50 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Oxytrol ; Oxytrol for women	oxybutynin td patch twice weekly	3.9 MG/24HR	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Toviaz	fesoterodine fumarate tab er	4 MG ; 8 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Vesicare	solifenacin succinate tab	10 MG ; 5 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Vesicare ls	solifenacin succinate susp	5 MG/5ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	<p><b>Quantity limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) is greater than the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> up to 12 months</p>