



Benign Prostatic Hypertrophy (BPH) Quantity Limit Program Summary

Quantity limits apply to Medicaid.

POLICY REVIEW CYCLE

Effective Date
10/1/2023

Date of Origin
9/1/2016

FDA APPROVED INDICATIONS AND DOSAGE

| Agent(s) | FDA Indication(s) | Notes | Ref# |
|----------|-------------------|-------|------|
| | | | |

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 |
|----------------------------|---|-------------|-----------|-----------|------------|----------|---------------|--------------------|-------------------------------------|
| | Terazosin HCl Cap 1 MG (Base Equivalent) | 1 ; 1 MG | 30 | Capsule | 30 | DAYS | | | |
| | Terazosin HCl Cap 10 MG (Base Equivalent) | 10 MG | 60 | Capsules | 30 | DAYS | | | |
| | Terazosin HCl Cap 2 MG (Base Equivalent) | 2 MG | 30 | Capsules | 30 | DAYS | | | |
| | Terazosin HCl Cap 5 MG (Base Equivalent) | 5 MG | 30 | Capsules | 30 | DAYS | | | |
| Avodart | Dutasteride Cap 0.5 MG | 0.5 MG | 30 | Tablets | 30 | DAYS | | | |
| Cardura | Doxazosin Mesylate Tab 1 MG | 1 MG | 30 | Tablets | 30 | DAYS | | | |
| Cardura | Doxazosin Mesylate Tab 2 MG | 2 MG | 30 | Tablets | 30 | DAYS | | | |
| Cardura | Doxazosin Mesylate Tab 4 MG | 4 MG | 30 | Tablets | 30 | DAYS | | | |
| Cardura | Doxazosin Mesylate Tab 8 MG | 8 MG | 60 | Tablets | 30 | DAYS | | | |
| Cardura xl | doxazosin mesylate tab er | 4 MG ; 8 MG | 30 | Tablets | 30 | DAYS | | | |
| Entadfi | Finasteride-Tadalafil Cap | 5-5 MG | 30 | Capsules | 30 | DAYS | | | |
| Flomax | Tamsulosin HCl Cap 0.4 MG | 0.4 MG | 60 | Capsules | 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 |
|----------------------------|---|-------------|-----------|-----------|------------|----------|---------------|--------------------|-------------------------------------|
| Jalyn | Dutasteride-Tamsulosin HCl Cap 0.5-0.4 MG | 0.5-0.4 MG | 30 | Capsules | 30 | DAYS | | | |
| Proscar | Finasteride Tab 5 MG | 5 MG | 30 | Tablets | 30 | DAYS | | | |
| Rapaflo | silodosin cap | 4 MG ; 8 MG | 30 | Capsules | 30 | DAYS | | | |
| Uroxatral | Alfuzosin HCl Tab ER 24HR 10 MG | 10 MG | 30 | Tablets | 30 | DAYS | | | |

CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|---|-------------|------------------|
| | Terazosin HCl Cap 1 MG (Base Equivalent) | 1 ; 1 MG | Medicaid |
| | Terazosin HCl Cap 10 MG (Base Equivalent) | 10 MG | Medicaid |
| | Terazosin HCl Cap 2 MG (Base Equivalent) | 2 MG | Medicaid |
| | Terazosin HCl Cap 5 MG (Base Equivalent) | 5 MG | Medicaid |
| Avodart | Dutasteride Cap 0.5 MG | 0.5 MG | Medicaid |
| Cardura | Doxazosin Mesylate Tab 1 MG | 1 MG | Medicaid |
| Cardura | Doxazosin Mesylate Tab 2 MG | 2 MG | Medicaid |
| Cardura | Doxazosin Mesylate Tab 4 MG | 4 MG | Medicaid |
| Cardura | Doxazosin Mesylate Tab 8 MG | 8 MG | Medicaid |
| Cardura xl | doxazosin mesylate tab er | 4 MG ; 8 MG | Medicaid |
| Entadfi | Finasteride-Tadalafil Cap | 5-5 MG | Medicaid |
| Flomax | Tamsulosin HCl Cap 0.4 MG | 0.4 MG | Medicaid |
| Jalyn | Dutasteride-Tamsulosin HCl Cap 0.5-0.4 MG | 0.5-0.4 MG | Medicaid |
| Proscar | Finasteride Tab 5 MG | 5 MG | Medicaid |
| Rapaflo | silodosin cap | 4 MG ; 8 MG | Medicaid |
| Uroxatral | Alfuzosin HCl Tab ER 24HR 10 MG | 10 MG | Medicaid |

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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

| Module | Clinical Criteria for Approval |
|--------|--|
| | <ol style="list-style-type: none"> 1. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication AND 2. Information has been provided to support therapy with a higher dose for the requested indication <p>Length of Approval: up to 12 months</p> |