



## Prior Authorization Approval Criteria

**Generic name:** Silodosin

**Brand name:** Rapaflo

**Medication class:** Alpha-1 adrenergic blocker

**FDA-approved uses:**

- Treatments of the signs and symptoms of benign prostatic hyperplasia

**Available dosage forms:** Oral capsule: 4 mg, 8 mg

**Usual dose:** 8 mg by mouth daily with a meal

**Approximate monthly cost:** \$113.10 (based on AWP 2009)

**Duration of therapy:** Clinical trials were conducted for 12 weeks

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

- Must have signs and symptoms of benign prostatic hyperplasia
- $\geq 18$  years old
- Tried and failed at least one generic alpha-1 adrenergic blocker
  - Doxazosin
  - Terazosin

**Criteria for continuation of therapy:**

- A decrease in obstructive and irritative symptoms associated with BPH
- Normal renal and hepatic function

**Caution:**

- Carcinoma of the prostate; rule out prior to initiation of therapy
- Concomitant use with other alpha-blockers or with strong P-glycoprotein inhibitors (eg, cyclosporine); use not recommended
- Intraoperative floppy iris syndrome may occur during cataract surgery
- Postural hypotension may occur when initiating therapy
- Renal impairment, moderate (CrCl of 30-50 mL/min); dose reduction recommended

**Monitoring:**

- Increase in peak urinary flow rates
- Reduction in obstructive and irritative symptoms
- Blood pressure for postural hypotension, including syncope

**Contraindication:**

- Concomitant use with a strong CYP 3A4 inhibitor (ketoconazole, clarithromycin, itraconazole, ritonavir)
- Severe hepatic impairment (Child-Pugh score of 10 or greater)
- Renal impairment (CrCl less than 30 mL/min)

**Not approved if:**

- Does not meet the above specifications

**Special considerations:**

- Only one published randomized controlled trial was found, in which silodosin was compared to low dose tamsulosin. Silodosin was found to be as effective as tamsulosin.
- Silodosin has significantly more contraindications and precautions compared to other alpha-1 adrenergic blockers.

<b>Drug</b>	<b>Daily Dose (max)</b>	<b>Tier</b>	<b>Cost</b>	<b>Generic available</b>
Alfuzosin Extended Release (Uroxatral)	10mg	3	\$112.00 10mg/day	No
Doxazosin-generic (Cardura)	8mg	1 3	\$24.00 8mg/day (generic pricing)	Yes
Doxazosin Extended Release (Cardura XL)	8mg	3	\$58.00 8mg/day	No
Prazosin-generic (Minipress)	20mg	1 3	\$25.00 5mg/day (generic pricing)	Yes
Silodosin (Rapaflo)	8mg	?	\$113.00 8mg/day	No
Tamsulosin (Flomax)	0.8mg	3	\$110.00 0.4mg/day	No
Terazosin-generic (Hytrin)	10mg	1 3	\$14.00 10mg/day (generic pricing)	Yes

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Adopted: 06/10/09