VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

SOMAVERT (Pegvisomant)

Effective Date: 1/28/14
Date Developed: 1/28/14 by Catherine Sanders, MD
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Somavert is an analogue of human growth hormone. Pegvisomant selectively binds to growth hormone (GH) receptors, blocking the binding of endogenous GH, leading to decreased serum concentrations of insulin-like growth factor-1 (IGF-I) and other GH-responsive proteins. Pegvisomant is made up of a recombinant DNA protein covalently bound to polyethylene glycol (PEG) polymers.

Pre-Authorization Criteria:
Somavert is used in the treatment of acromegaly in patients resistant to or unable to tolerate other therapies such as a long acting somatostatin analog and if surgery is not expected to result in complete resection of the adenoma.
The manufacturer recommends the initial dose be administered under the supervision of the prescribing healthcare provider.

Dosing: Adult:
Acromegaly: SubQ: Initial loading dose: 40 mg; maintenance dose: 10 mg once daily; doses may be adjusted by 5 mg increments in 4- to 6-week intervals based on IGF-I concentrations (maximum maintenance dose: 30 mg/day)

Dosing: Geriatric:
Refer to adult dosing.

Dosing: Renal Impairment:
No dosage adjustment provided in manufacturer's labeling (has not been studied).

Dosing: Hepatic Impairment:
At initiation of therapy:
Normal liver function test (LFT): Initiate therapy; monitor LFT monthly for first 6 months, quarterly for next 6 months, then biannually the following year.
Baseline LFT elevated but ≤3 x ULN: May initiate therapy with monthly evaluation of LFT for 1 year then biannually the following year.
Baseline LFT >3 times ULN: Do not initiate treatment without comprehensive work-up to determine cause; monitor closely if treatment is started.
With ongoing therapy:
LFT ≥3 x but <5 x ULN without signs/symptoms of hepatitis, hepatic injury, or increase in total bilirubin: Continue treatment, but monitor LFT weekly for further increases; perform comprehensive hepatic work-up to rule out alternative cause of hepatic dysfunction

LFT ≥5 x ULN or transaminase ≥3 x ULN associated with any increase in total bilirubin: Discontinue immediately and perform comprehensive hepatic work-up. If LFTs return to normal, may cautiously consider restarting therapy with frequent LFT monitoring.
Signs or symptoms of hepatitis or hepatic injury: Discontinue therapy immediately and perform comprehensive hepatic work-up; discontinue permanently if liver injury is confirmed.

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution Reconstituted, Subcutaneous:
Somavert: 10 mg (1 ea); 15 mg (1 ea); 20 mg (1 ea)

Generic Equivalent Available: U.S.-No

Administration:
For SubQ administration only; to minimize the risk for lipohypertrophy, rotate injection site daily; may administer in upper arm, thigh, abdomen, or buttocks; do not rub injection site. The manufacturer recommends the initial dose be administered under the supervision of prescribing healthcare provider.

Adverse Reactions:
>10%: pain, diarrhea, nausea, liver function tests abnormal, infection site reaction, infection, non-neutralizing anti-GH antibodies, flu-like syndrome.
Other Serious Less Common Reactions:

References:

1. www.uptodate.com: Pervisomant: Drug Information
2. www.uptodate.com: Acromegaly Treatment
3. www.epocrates.com: Somavert Drug information

Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
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