Consensi

Description

Consensi (amlodipine besylate and celecoxib)

Background
Consensi is a combination of amlodipine besylate, a calcium channel blocker used to treat hypertension, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID) used to treat pain in patients with osteoarthritis. Celecoxib (brand name Celebrex) is believed to work by inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2). Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure (1).

Regulatory Status
FDA approved indication: Consensi is a combination of amlodipine besylate, a calcium channel blocker, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions (1).

Consensi has a boxed warning due to the NSAID component (celecoxib), of gastrointestinal, cardiovascular, and bleeding risks. Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use. Consensi is contraindicated in the setting of coronary artery bypass graft
(CABG) surgery. NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events (1).

The safety and effectiveness of Consensi in pediatric patients have not been established (1).

**Related policies**
Celebrex, Celebrex powder

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Consensi may be considered medically necessary for patients 18 years of age and older for hypertension and osteoarthritis and if the conditions below are met.

Consensi may be considered investigational in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age and older

**Diagnoses**

Patient must have BOTH of the following:

1. Hypertension
2. Osteoarthritis

AND ALL of the following:

a. Inadequate treatment response to a 3-month trial of amlodipine and celecoxib separately
b. NO dual therapy with other celecoxib products (Celebrex)
Prior–Approval Renewal Requirements

Age
18 years of age and older

Diagnoses

Patient must have BOTH of the following:

1. Hypertension
2. Osteoarthritis

AND the following:
   a. NO dual therapy with other celecoxib products (Celebrex)

Policy Guidelines

Pre–PA Allowance
None

Prior–Approval Limits

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>2.5 mg/200 mg</td>
<td>90 tablets per 90 days</td>
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<tr>
<td>5 mg/200 mg</td>
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<tr>
<td>10 mg/200 mg</td>
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Duration
12 months

Prior–Approval Renewal Limits
Same as above
Rationale

Summary
Consensi is a combination of amlodipine besylate, a calcium channel blocker used to treat hypertension, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID) used to treat pain in patients with osteoarthritis. Consensi has a boxed warning due to the NSAID component (celecoxib), of gastrointestinal, cardiovascular, and bleeding risks. Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Consensi while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>June 2018</td>
<td>Addition to PA</td>
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<tr>
<td>September 2018</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 20, 2018 and is effective on October 1, 2018.