Doxylamine Pyridoxine

**Description**

Bonjesta, Diclegis (doxylamine-pyridoxine)

**Background**

Nausea and vomiting of pregnancy (NVP) is a common problem that afflicts approximately 44 – 89% of pregnant women during their pregnancies. NVP generally starts around 4-6 weeks of pregnancy, peaks around 8 – 12 weeks, and then tapers off after around 20 weeks (however recent evidence suggests many women may experience NVP throughout pregnancy, even into late pregnancy). Conservative measures are often recommended before medications. Conservative measures involve dietary and lifestyle changes, which include: eating smaller and more frequent meals, staying adequately hydrated, and resting appropriately. Once conservative measures have failed, medications are used. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B₆) and doxylamine succinate (Unisom®) which are available separately over the counter. Legend medications, Diclegis and Bonjesta, include both of these agents in one tablet and are available with a prescription (1-5).

**Regulatory Status**

FDA approved indication: Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B₆ analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (4-5).

Diclegis contains 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride in a delayed release dosage form. Bonjesta consist of an enteric-coated core containing 10 mg
doxylamine succinate and 10 mg pyridoxine hydrochloride, and an immediate release coating of 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride. These medications are intended to be taken on a daily basis and not as needed for nausea (physician must reassess patient throughout pregnancy to determine if continued use is needed) (4-5).

The safety and effectiveness of Bonjesta and Diclegis in pediatric patients have not been established (4-5).

**Related policies**
5HT3 Antagonists, Cannabinoids, NK-1 Antagonists

**Policy**

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

Bonjesta and Diclegis are **medically necessary** for pregnant women 18 years of age and older experiencing nausea and vomiting of pregnancy (NVP) and if the conditions indicated below are met.

Bonjesta and Diclegis are **investigational** for people under 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

- Nausea and/or vomiting of pregnancy (NVP)

**AND ALL** of the following:

1. Patient has failed conservative measurements (Appendix 1)
2. Inadequate treatment response, or intolerance to doxylamine (e.g. Unisom®) and pyridoxine (Vitamin B₆) separately.

3. Prescriber agrees to monitor the patient during pregnancy to determine whether continued use of the medication is needed.

Prior–Approval Renewal Requirements
None

Policy Guidelines

Pre–PA Allowance
None

Prior–Approval Limits

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>Diclegis</td>
<td>360 tablets per 90 days OR</td>
</tr>
<tr>
<td>Bonjesta</td>
<td>180 tablets per 90 days</td>
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</tbody>
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Duration 9 months – Only 1 Prior Authorization allowed per pregnancy

Prior–Approval Renewal Limits
None

Rationale

Summary
Nausea and vomiting of pregnancy (NVP) is a common problem that afflicts approximately 44 – 89% of pregnant women during their pregnancies. Conservative measures are often recommended before medications. The pregnancy category A medication(s) of choice include pyridoxine hydrochloride (Vitamin B₆) and doxylamine succinate (Unisom®) which are available separately over the counter. Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management (1-5).
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Bonjesta and Diclegis while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.
Appendix 1

<table>
<thead>
<tr>
<th>Conservative Measures for NVP</th>
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<tbody>
<tr>
<td>Maintain adequate hydration (2 liters of water daily)</td>
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<tr>
<td>Eat small, frequent meals, avoiding a full or empty stomach</td>
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<tr>
<td>Eat bland foods, avoid spicy and odorous foods</td>
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<tr>
<td>Take frequent naps</td>
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<tr>
<td>Consume ice chips or very cold beverages</td>
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<tr>
<td>Eat simple dry carbohydrates (like crackers) prior to getting out of bed in the morning</td>
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</table>