



Bonjesta Diclegis Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|-----------------------|--|----------|---------------|---------------|-----------------|------------------|
| Diclegis | Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG | 10-10 MG | M ; N ; O ; Y | O ; Y | | |
| Bonjesta | doxylamine-pyridoxine tab er | 20-20 MG | M ; N ; O ; Y | N | | |

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 |
|----------------------------|--|----------|-----------|-----------|------------|----------|---------------|--------------------|-------------------------------------|
| Bonjesta | Doxylamine-Pyridoxine Tab ER 20-20 MG | 20-20 MG | 60 | Tablets | 30 | DAYS | | | |
| Diclegis | Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG | 10-10 MG | 120 | Tablets | 30 | DAYS | | | |

CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------|---|
| Bonjesta | doxylamine-pyridoxine tab er | 20-20 MG | IL HMO Performance Annual ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|--|----------|--|
| | | | Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 |
| Diclegis | Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG | 10-10 MG | IL HMO Performance Annual ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 |

CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|--|----------|--|
| Bonjesta | Doxylamine-Pyridoxine Tab ER 20-20 MG | 20-20 MG | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods |
| Diclegis | Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG | 10-10 MG | IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------|--|
| | | | Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods |

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|--------|--|
| | <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is being used to treat pregnancy related nausea or vomiting (not including hyperemesis gravidarum) OR B. The patient has another FDA labeled indication for the requested agent and route of administration AND 2. ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The prescriber states the patient is currently being treated with a requested agent AND the patient is currently stable on the requested agent [chart notes required] OR C. The patient has tried and had an inadequate response to the use of the individual ingredients within the target combination agent as separate dosage forms [chart notes required] OR D. The use of the individual ingredients within the target combination agent as separate dosage forms was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR E. The patient has an intolerance or hypersensitivity to the use of the individual ingredients within the target combination agent as separate dosage forms (that is not expected to happen with the requested agent) [chart notes required] OR F. The patient has an FDA labeled contraindication to the use of the individual ingredients within the target combination agent as separate dosage forms (that is not expected to happen with the requested agent) [chart notes required] OR G. The use of the individual ingredients within the target combination agent as separate dosage forms is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR H. The use of the individual ingredients within the target combination agent as separate dosage forms is not in the best interest of the patient based on medical necessity [chart notes required] OR I. The patient has tried another drug in the same pharmacologic class or with the same mechanism of action as the individual ingredients in the requested agent and that drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR J. There is support that the use of the individual ingredients within the target combination agent as separate dosage forms is not clinically appropriate for the patient AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSIL and BCBSMT: Up to due date of pregnancy or 6 months, whichever is longer</p> |

| Module | Clinical Criteria for Approval |
|--------|---|
| | <p>BCBSNM: Up to due date of pregnancy or 3 months, whichever is longer</p> <p>ALL other plans: Up to due date of pregnancy</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> |

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|--------|--|
| | <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) exceeds 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 |

| Module | Clinical Criteria for Approval |
|--------|---|
| | <p style="margin-left: 40px;">2. There is support for therapy with a higher dose for the requested indication OR</p> <p>B. BOTH of the following:</p> <p style="margin-left: 40px;">1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND</p> <p style="margin-left: 40px;">2. There is support for 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</p> <p>C. BOTH of the following:</p> <p style="margin-left: 40px;">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND</p> <p style="margin-left: 40px;">2. There is support for therapy with a higher dose for the requested indication</p> <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>ALL other plans: Up to due date of pregnancy.</p> |