

## PHARMACY COVERAGE GUIDELINE

### VOQUEZNA® (vonoprazan) Generic Equivalent (if available)

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#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
  - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
  - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
  - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
  - The “Description” section describes the Service.
  - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
  - The “Resources” section lists the information and materials we considered in developing this PCG
  - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
  - Information about medications that require prior authorization available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).
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## Medical Necessity Requirements for VOQUEZNA (vonoprazan)

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### Criteria for Initial Therapy:

#### **Prescriber Qualifications**

- Prescribed by a Gastroenterologist or in consultation with a Gastroenterologist

#### **Indication**

- Healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis
- Maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis
- Relief of heartburn associated with non-erosive gastroesophageal reflux disease (NERD)

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- Treatment of *Helicobacter pylori* (*H. pylori*) infection in combination with amoxicillin and clarithromycin or in combination with amoxicillin alone

#### Age Requirement

- 18 years or older

#### Baseline Clinical Evaluation

- Serum magnesium and calcium levels
- **For erosive esophagitis, ALL** the following:
  - Endoscopic confirmation of erosive esophagitis
  - Los Angeles classification grade C or D
  - Heartburn symptoms two or more times per week
- **For non-erosive gastroesophageal reflux disease (NERD), ALL** the following:
  - History of heartburn for 6 months or longer
  - Heartburn on at least 4 of 7 days
  - No esophageal erosions on endoscopy
  - Negative for *H. pylori* infection
- **For Helicobacter pylori infection:**
  - Positive <sup>13</sup>C urea breath test (UBT)
  - **ONE** of the following:
    1. Dyspepsia for at least 2 weeks
    2. Functional dyspepsia
    3. Recent or new diagnosis of non-bleeding peptic ulcer
    4. History of peptic ulcer not previously treated for *H. pylori* infection
    5. Requires long-term non-steroidal anti-inflammatory drug treatment using a stable dose

#### Alternative Therapies

- **For erosive esophagitis/heartburn:**
  - **TWO** of the following proton pump inhibitors used at two times the standard doses:
    1. Dexlansoprazole: 30 mg twice daily
    2. Esomeprazole: 20 mg twice daily
    3. Lansoprazole: 30 mg twice daily
    4. Omeprazole: 20 mg twice daily
    5. Pantoprazole: 40 mg twice daily
    6. Rabeprazole: 20 mg twice daily
- **For non-erosive gastroesophageal reflux disease (NERD):**
  - Use of standard doses of **TWO** of the following:
    1. Dexlansoprazole: 30 mg once daily
    2. Esomeprazole: 20 mg once daily
    3. Lansoprazole: 30 mg once daily
    4. Omeprazole: 20 mg once daily
    5. Pantoprazole: 40 mg once daily

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- 6. Rabeprazole: 20 mg once daily
- **For Helicobacter pylori infection:**
  - **Without risk factors for macrolide resistance, ONE** of the following:
    1. A proton pump inhibitor, amoxicillin, and clarithromycin
    2. A proton pump inhibitor, metronidazole, and clarithromycin
  - **With risk factors for macrolide resistance:** A proton pump inhibitor, metronidazole, tetracycline, and bismuth subsalicylate

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No concomitant use with:
  - Atazanavir or nelfinavir
  - Moderate or strong CYP3A4 inducers
  - Rilpivirine-containing products
- For Helicobacter pylori infection only:
  - Will not be used if estimated glomerular filtration rate is less than 30 mL/min
  - Will not be used in moderate to severe hepatic impairment (Child-Pugh Class B and C)

#### Documentation Requirements

- A completed request form must be submitted, including:
  - Chart notes
  - Lab results (including serum magnesium and calcium levels, endoscopy findings, <sup>13</sup>C urea breath test)
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 14 days: Helicobacter pylori infection
- 4 weeks: Relief of heartburn associated with non-erosive gastroesophageal reflux disease (NERD)
- 8 weeks: Healing of erosive esophagitis
- 6 months: Maintenance of erosive esophagitis
- OR end of plan year

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### Criteria for Continuation of Therapy (renewal therapy)

**Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy**

#### Prescriber Qualification

- Continues to be seen by a physician specializing in or is in consultation with a Gastroenterologist

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#### Clinical Response

- **For erosive esophagitis healing:**
  - Endoscopic evidence of complete healing
  - Increased number of days without heartburn
  - Maintains healing and resolution of heartburn symptoms
- **For non-erosive gastroesophageal reflux disease (NERD):**
  - Increased number of days without daytime or nighttime heartburn
  - Increase in the number of days without rescue antacids
- **For Helicobacter pylori infection:**
  - Renewal requests will be evaluated using criteria from Initial Therapy
  - Multiple requests for renewal treatment will not be approved and will be forwarded to Utilization Management for review

#### Adherence

- Adherence to the prescribed therapy regimen has been documented

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No significant drug-drug interactions or contraindications such as:
  - Acute tubulointerstitial nephritis
  - Severe cutaneous reactions (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis)
  - Hypomagnesemia refractory to treatment
  - Hypocalcemia refractory to treatment
- No concomitant use with:
  - Atazanavir or nelfinavir
  - Moderate or strong CYP3A4 inducers
  - Rilpivirine-containing products

#### Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

#### Continuation Therapy Criteria Approval Duration

- 12 months: Maintenance of erosive esophagitis
- 4 weeks: Relief of heartburn associated with non-erosive gastroesophageal reflux disease (NERD)
- OR end of plan year

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#### Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
  2. Off-Label Use of Cancer Medications
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#### Description:

Voquezna (vonoprazan) is a potassium-competitive acid blocker indicated for both healing and to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. Voquezna (vonoprazan) is also indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults in combination with amoxicillin and clarithromycin or in combination with amoxicillin alone.

Vonoprazan suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H<sup>+</sup>, K<sup>+</sup>-ATPase enzyme system in a potassium competitive manner. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, vonoprazan has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production. Vonoprazan does not require activation by acid. Vonoprazan may selectively concentrate in the parietal cells in both the resting and stimulated states. Vonoprazan binds to the active pumps in a noncovalent and reversible manner.

Gastroesophageal reflux disease (GERD) is a condition that develops when stomach contents are refluxed into the esophagus and cause troublesome symptoms and/or complications. The term GERD covers a spectrum of conditions, including endoscopy-negative GERD (aka NERD), erosive esophagitis (EE), and Barrett's esophagus (BE). GERD may be defined as the presence of at least weekly heartburn and/or regurgitation. Non-erosive gastroesophageal reflux disease (NERD) individuals satisfy the definition of GERD but do not have either BE or definite endoscopic esophageal mucosal breaks (erosions or ulcerations).

The endoscopic classification of EE, utilizing the LA Grade Classification, applies the appearance of a mucosal break, defined as an area of slough or erythema with a sharp line of demarcation from adjacent normal mucosa, in the grading. EE is then graded from "A-D", according to the extent of mucosal break seen on endoscopy. Proton pump inhibitors (PPIs), such as lansoprazole or omeprazole, are effective anti-secretory agents for relieving GERD symptoms, healing the injured mucosa, and maintaining a healed mucosa. However, it is estimated that up to 40% of individuals report suboptimal response to once daily PPI therapy and as such many are prescribed twice daily dosing of PPIs. LA Classification grades C or D (corresponding to moderate to severe EE) have shown suboptimal healing rates of 62% to 84% after 8 weeks of treatment with a PPI. NERD is a non-progressive disease and treatment of NERD is symptom-driven and includes use of PPIs for 4-8 weeks.

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#### Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

#### **Los Angeles Classification of Esophagitis Grading Scale:**

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LA Grade Classification	
Grade A	One or more <u>mucosal breaks</u> with a <u>length</u> of <b>no longer</b> than 5 mm that does not extend between the tops of 2 mucosal folds
Grade B	One or more <u>mucosal breaks</u> with a <u>length</u> of <b>longer</b> than 5 mm that does not extend between the tops of 2 mucosal folds
Grade C	One or more <u>mucosal breaks</u> that are <u>continuous</u> between the tops of 2 or more mucosal folds, which involves less than 75% of the circumference
Grade D	One or more <u>mucosal breaks</u> , which involves at least 75% of the circumference
A mucosal break is defined as “an area of slough or erythema with a sharp line of demarcation from adjacent normal mucosa”	

**Definitions of Heartburn Severity (Daytime/Nighttime):**

Definitions of Daytime Heartburn Severity (Daytime/Awake Time)	
None	No heartburn
Mild	Occasional heartburn, can be ignored, does not influence daily routine
Moderate	Heartburn cannot be ignored and/or occasionally influences daily routine
Severe	Heartburn present most of day and/or regularly influences daily routine
Very severe	Constant heartburn and/or markedly influences daily routine
Definitions of Nighttime Heartburn Severity (Nighttime/Sleep Time)	
None	No heartburn
Mild	Occasional heartburn, can be ignored, does not influence sleep
Moderate	Heartburn cannot be ignored and/or occasionally influences sleep
Severe	Heartburn present most of night and/or regularly influences sleep
Very severe	Constant heartburn and/or markedly influences sleep

**Treatment of Gastroesophageal Reflux Disease in Adults:**

	Low dose (oral)	Standard dose (oral)	High dose (oral)
<b>Histamine 2 receptor antagonists (H2RA)*</b>			
Cimetidine <sup>§</sup>	200 mg twice daily	400 mg twice daily <sup>Δ</sup>	Not recommended
Famotidine	10 mg twice daily	20 mg twice daily <sup>Δ</sup>	40 mg twice daily
Nizatidine	75 mg twice daily <sup>◇</sup>	150 mg twice daily	300 mg twice daily
<b>Proton pump inhibitors (PPIs): (H-K) ATPase Pump</b>			

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Dexlansoprazole	Not available	30 mg daily <sup>Δ</sup>	60 mg once daily or 30 mg twice daily
Esomeprazole	20 mg daily <sup>¥</sup>	40 mg daily	40 mg twice daily
Lansoprazole	15 mg daily	30 mg daily	30 mg twice daily
Omeprazole	10 mg daily	20 mg daily	40 mg once daily or 20 mg twice daily
Pantoprazole	20 mg daily	40 mg daily	40 mg twice daily
Rabeprazole	10 mg daily <sup>¥</sup>	20 mg daily	20 mg twice daily
<b>Potassium-competitive acid blocker (PCABs): (H-K) ATPase Pump</b>			
Vonoprazan	10 mg once daily	20 mg once daily	20 mg twice daily
<p>* Histamine 2 receptor antagonists require dose adjustment in the setting of renal insufficiency.</p> <p>Δ The <b>daily dose for erosive esophagitis with symptoms of GERD</b> in the US prescribing information is <b>up to twice the standard dose shown in this table</b>.</p> <p>◇ Strength not available in US. Available elsewhere.</p> <p>§ Significant drug interactions can occur. When initiating or altering drug therapy, use of a drug interactions database, such as the drug interactions program, is advised. Other histamine 2 receptor antagonists with more favorable adverse effect profiles and fewer drug interactions (e.g., famotidine) are generally preferred.</p> <p>¥ Dose strength limited to certain dosage forms (e.g., granules for oral suspension or sprinkle capsule).</p> <p>Consult local product availability.</p>			

#### **Risk factors for Barrett's esophagus:** (must have a duration of GERD of at least 5-10 years)

- Age 50 years or older
- Male sex
- White individuals
- Hiatal hernia
- Obesity
- Nocturnal reflux
- Tobacco use (past or current)
- First-degree relative with Barrett's esophagus and/or adenocarcinoma

#### **Alarm features suggestive of a gastrointestinal malignancy:**

- New onset of dyspepsia in patient ≥60 years
- Evidence of gastrointestinal bleeding (hematemesis, melena, hematochezia, occult blood in stool)
- Iron deficiency anemia
- Anorexia
- Unexplained weight loss
- Dysphagia
- Odynophagia
- Persistent vomiting
- Gastrointestinal cancer in a first-degree relative

#### **Some examples of Cytochrome P450 Interactions: (Not a complete list)**

**CYP2C19**

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Strong Inducer	Moderate Inducer	Strong Inhibitor	Moderate Inhibitor
rifampin	carbamazepine, dabrafenib, enzalutamide, letermovir, phenytoin derivatives, Saint John's wort, tipranavir/ritonavir	delavirdine, fluconazole, fluvoxamine, ticlopidine	armodafinil, cimetidine, eslicarbazepine, esomeprazole, felbamate, fluoxetine, isoniazid, modafinil, omeprazole, oxcarbazepine, voriconazole
<b>CYP3A4</b>			
Strong Inducer	Moderate Inducer	Strong Inhibitor	Moderate Inhibitor
carbamazepine, phenobarbital, phenytoin derivatives, primidone, rifabutin, rifampin, rifapentine, rufinamide, Saint John's wort	armodafinil, bexarotene, bosentan, dabrafenib, deferasirox, dexamethasone, efavirenz, modafinil, nafcillin, nevirapine, oxcarbazepine	clarithromycin, isoniazid, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, ritonavir, telaprevir, telithromycin, tipranavir/ritonavir, voriconazole	amiodarone, aprepitant, cyclosporine, diltiazem, dronedarone, erythromycin, fluconazole, fluvoxamine, grapefruit juice, isavuconazonium, netupitant, verapamil, zafirlukast

### Resources:

Voquezna (vonoprazan) product information, revised by Phathom Pharmaceuticals, Inc. 07-2024. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 18, 2025.

Kahrilas PJ. Clinical manifestations and diagnosis of gastroesophageal reflux disease in adults. In: UpToDate, Talley NJ, Swenson S, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through February 2025. Topic last updated October 16, 2024. Accessed March 13, 2025.

Kahrilas PJ. Initial management of gastroesophageal reflux disease in adults. In: UpToDate, Talley NJ, Swenson S, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through February 2025. Topic last updated February 21, 2025. Accessed March 13, 2025.

Fass Ronnie. Approach to refractory gastroesophageal reflux disease in adults. In: UpToDate, Talley NJ, Robson KM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through February 2025. Topic last updated May 14, 2024. Accessed March 13, 2025.

Shah SC, Kao JY, Moss SF. Treatment regimens for Helicobacter pylori in adults. In: UpToDate, Talley NJ, Swenson S, Meyer C (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through February 2025. Topic last updated March 05, 2025. Accessed March 13, 2025.

Bergsland E, Ge PS. Management and prognosis of Zollinger-Ellison syndrome (gastrinoma). In: UpToDate, Laine L, Shah SM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through February 2025. Topic last updated December 04, 2024. Accessed March 14, 2025.

Laine L, DeVault K, Katz P, et al.: Vonoprazan Versus Lansoprazole for Healing and Maintenance of Healing of Erosive Esophagitis: A Randomized Trial. Gastroenterology 2023;164(1) :61–71. Accessed February 23, 2024. Re-evaluation March 13, 2025.

Targownik LE, Fisher DA, Saini SD. AGA Clinical Practice Update on De-Prescribing of Proton Pump Inhibitors: Expert Review. Gastroenterology 2022 April; 1 (4); 162:1334–1342. Accessed February 29, 2024. Re-evaluation March 13, 2025.

Katz PO, Dunbar K, Schnoll-Sussman FH, et al.: ACG Clinical Guideline: Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2022 January 01; 117(1): 27–56. Accessed March 04, 2024. Re-evaluation March 13, 2025.

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ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04124926: A Phase 3, Randomized, Double-Blind, Two Phase, Multicenter Study to Evaluate the Efficacy and Safety of Vonoprazan 20 mg Compared to Lansoprazole 30 mg for Healing in Patients With Erosive Esophagitis and to Evaluate the Efficacy and Safety of Vonoprazan (10 mg and 20 mg) Compared to Lansoprazole 15 mg for the Maintenance of Healing in Patients With Healed Erosive Esophagitis. Available from: <http://clinicaltrials.gov>. Last update posted July 29, 2022. Last verified July 2022. Accessed February 23, 2024. Re-evaluation March 13, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04124926: Protocol Number: EE-301. A Phase 3, Randomized, Double-Blind, Two Phase, Multicenter Study to Evaluate the Efficacy and Safety of Vonoprazan 20 mg Compared to Lansoprazole 30 mg for Healing in Patients With Erosive Esophagitis and to Evaluate the Efficacy and Safety of Vonoprazan (10 mg and 20 mg) Compared to Lansoprazole 15 mg for the Maintenance of Healing in Patients With Healed Erosive Esophagitis. Available from: <http://clinicaltrials.gov>. October 01, 2019. Accessed February 23, 2024. Re-evaluation March 13, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04167670: A Phase 3 Randomized Multicenter Study to Evaluate the Efficacy and Safety of Open-Label Dual Therapy With Oral Vonoprazan 20 mg or Double-Blind Triple Therapy With Oral Vonoprazan 20 mg Compared to Double-Blind Triple Therapy With Oral Lansoprazole 30 mg Daily in Patients With Helicobacter Pylori Infection. Available from: <http://clinicaltrials.gov>. Last update posted April 05, 2022. Last verified March 2022. Accessed February 23, 2024. Re-evaluation March 13, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT04167670: Protocol Number: HP-301. A Phase 3 Randomized Multicenter Study to Evaluate the Efficacy and Safety of Open-Label Dual Therapy With Oral Vonoprazan 20 mg or Double-Blind Triple Therapy With Oral Vonoprazan 20 mg Compared to Double-Blind Triple Therapy With Oral Lansoprazole 30 mg Daily in Patients With Helicobacter Pylori Infection. Available from: <http://clinicaltrials.gov>. Last update posted April 05, 2022. Last verified March 2022. Accessed February 23, 2024. Re-evaluation March 13, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT05195528: A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of Vonoprazan 10 and 20 mg Compared to Placebo for Relief of Heartburn in Subjects With Symptomatic Non-Erosive Gastroesophageal Reflux Disease (NERD) After 4 Weeks and to Evaluate the Efficacy and Safety of Vonoprazan 10 and 20 mg for Relief of Heartburn in Subjects With NERD After 6 Months. Available from: <http://clinicaltrials.gov>. Last update posted December 29, 2023. Last verified December 2023. Accessed March 14, 2025.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT05195528: Protocol Number: NERD-301. A Phase 3, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of Vonoprazan 10 and 20 mg Compared to Placebo for Relief of Heartburn in Subjects With Symptomatic Non-Erosive Gastroesophageal Reflux Disease (NERD) After 4 Weeks and to Evaluate the Efficacy and Safety of Vonoprazan 10 and 20 mg for Relief of Heartburn in Subjects With NERD After 6 Months. Available from: <http://clinicaltrials.gov>. Last update posted December 29, 2023. Last verified December 2023. Accessed March 14, 2025.