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PHARMACY POLICY – 5.01.590

Bruton's Kinase Inhibitors

Effective Date:	Mar. 1, 2025	RELATED MEDICAL POLICIES:	
Last Revised:	Feb. 11, 2025	5.01.543	General Medical Necessity Criteria for Companion Diagnostics Related to Drug Approval
Replaces:	N/A		

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

An enzyme is a chemical messenger. Tyrosine kinases are enzymes within cells. They serve as on/off switches for many of the cells' functions. One of their most important roles is to help send signals telling a cell to grow. If there is a genetic change that leaves the switch permanently on, cells grow without stopping and tumors form. Bruton's kinase inhibitors block the "grow" signal in specific types of tumors. This policy discusses when Bruton's tyrosine kinase inhibitors may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Brukinsa (zanubrutinib)	**Brukinsa (zanubrutinib) may be considered medically necessary when ALL the following criteria are met:** • The individual is aged 18 years or older

Drug	Medical Necessity

	AND
	• Meets ONE of the following:
	  ○ Diagnosed with mantle cell lymphoma (MCL) AND has received at least one prior therapy
	  ○ Diagnosed with Waldenström's macroglobulinemia (WM)
	  ○ Diagnosed with relapsed or refractory marginal zone lymphoma (MZL) AND has received at least one anti-CD20-based regimen (e.g., rituximab)
	  ○ Diagnosed with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
	  ○ Diagnosed with relapsed or refractory follicular lymphoma AND Brukinsa (zanubrutinib) will be used in combination with obinutuzumab after two or more lines of systemic therapy

Calquence (acalabrutinib)	**Calquence (acalabrutinib) may be considered medically necessary when ALL the following criteria are met:**
	• The individual is aged 18 years or older
	AND
	• Meets ONE of the following:
	  ○ Bruton's tyrosine kinase (BTK) inhibitor-naïve adult individuals with relapsed or refractory mantle cell lymphoma (MCL)
	  AND
	  ○ Tried one prior chemotherapy regimen (rituximab alone or rituximab containing regimen, CHOP-based, cytarabine, bendamustine + rituximab, Hyper-CVAD), or stem-cell transplant
	OR
	  ○ Previously untreated MCL in individuals who are ineligible for autologous hematopoietic stem cell transplantation (HSCT) and Calquence (acalabrutinib) is being used in combination with bendamustine and rituximab
	OR
	  ○ Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion

Imbruvica (ibrutinib)	**Imbruvica (ibrutinib) may be considered medically necessary when ALL the following criteria are met:**

Drug	Medical Necessity

	• The individual is aged 18 years or older
	AND
	• Meets ONE of the following:
	  ○ Diagnosed with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion
	  ○ Diagnosed with Waldenstrom macroglobulinemia
	
	Imbruvica (ibrutinib) may be considered medically necessary for the treatment of chronic graft versus host disease (cGVHD) when all the following criteria are met:
	• The individual is aged 1 year or older
	AND
	• Has had failure of one or more lines of systemic therapy

Jaypirca (pirtobrutinib)	**Jaypirca (pirtobrutinib) may be considered medically necessary for the treatment of mantle cell lymphoma when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with relapsed or refractory mantle cell lymphoma (MCL) after ≥ 2 lines of systemic therapy **AND** • Has been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., acalabrutinib, ibrutinib, zanubrutinib) **Jaypirca (pirtobrutinib) may be considered medically necessary for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has received ≥ 2 prior lines of therapy **AND** • Has been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., ibrutinib or acalabrutinib) **AND**

Drug	Medical Necessity
	• Has been previously treated with a B-cell lymphoma 2 (BCL-2) inhibitor (e.g., venetoclax)

Drug	Investigational
As listed	**All other uses of the medications listed in this policy are considered investigational.** **The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews for all drugs listed in the policy may be approved up to 12 months.** **All other reviews for all drugs listed in policy may be approved up to 3 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for re-authorization of all drugs listed in the policy may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

N/A

Related Information

Benefit Application

The drugs in this policy are managed through the pharmacy benefit.

Evidence Review

Description

Cancer is characterized by the uncontrolled growth and spread of malignant cells. Excluding non-melanoma skin cancers, over 2 million Americans will be diagnosed with cancer in 2025 and approximately 618,000 will die of the disease. The good news is survival rates for cancer are on the rise and over the past decade (2013-2022), the cancer death rate dropped by 1.7% per year.

Conventional cytotoxic cancer chemotherapy has been one of the major medical advances realized in the last few decades. Although directed toward certain biologic targets thought to be involved in cellular growth and proliferation, typically these drugs have not discriminated well between rapidly dividing normal cells (e.g., bone marrow, gastrointestinal tract) and tumor cells, frequently resulting in toxicities. In addition, tumor responses to traditional cytotoxic cancer chemotherapies can be unpredictable and brief.

"Targeted chemotherapies" are the newest therapeutic approach. This category includes the Bruton's tyrosine kinase inhibitors, which are small molecule agents that bind to the intracellular domain of the Bruton's kinase protein.

The Bruton's kinase inhibitors currently available are as follows:

Drug Name	Targets	FDA-Approved Uses
Acalabrutinib (Calquence)	Bruton's Tyrosine Kinase (BTK)	MCL, CLL/SLL
Ibrutinib (Imbruvica)	Bruton's Tyrosine Kinase (BTK)	MCL, CLL/SLL, WM, MZL, cGVHD
Pirtobrutinib (Jaypirca)	Bruton's Tyrosine Kinase (BTK)	MCL

Drug Name	Targets	FDA-Approved Uses
Zanubrutinib (Brukinsa)	Bruton's Tyrosine Kinase (BTK)	MCL, WM, MZL

MCL = Mantle cell lymphoma; CLL = Chronic lymphocytic leukemia; SLL = Small lymphocytic lymphoma; WM = Waldenström's macroglobulinemia; MZL = Marginal zone lymphoma; cGVHD = Chronic graft versus host disease

Summary of Evidence

Calquence (acalabrutinib)

Calquence (acalabrutinib) is a selective and irreversible second-generation Bruton's tyrosine kinase inhibitor. The efficacy was based upon Trial LY-004, which was an open-label phase 2 study with 124 individuals with mantle cell lymphoma who had been on at least one prior therapy. The primary outcome was the overall response rate (ORR). The study had 81 individuals who had an overall response rate, 40 individuals had a complete response, and 41 individuals had a partial response.

The efficacy of Calquence in individuals with CLL was demonstrated in two randomized, controlled trials called ELEVATE-TN and ASCEND. The indication for Calquence includes individuals with SLL because it is the same disease.

ELEVATE-TN

The efficacy of Calquence was evaluated in the ELEVATE-TN trial, a randomized, multicenter, open-label, actively controlled, 3 arm trial of Calquence in combination with obinutuzumab, Calquence monotherapy, and obinutuzumab in combination with chlorambucil in 535 individuals with previously untreated chronic lymphocytic leukemia. Individuals 65 years of age or older or between 18 and 65 years of age with a total Cumulative Illness Rating Scale (CIRS) > 6 or creatinine clearance of 30 to 69 mL/min were enrolled.

Individuals were randomized in a 1:1:1 ratio into 3 arms to receive:

- Calquence plus obinutuzumab (Calquence+G)
- Calquence monotherapy
- Obinutuzumab plus chlorambucil (GClb)

Randomization was stratified by 17p deletion mutation status, ECOG performance status (0 or 1 versus 2), and geographic region. A total of 535 individuals were randomized, 179 to

Calquence+G, 179 to Calquence monotherapy, and 177 to GClb. The overall median age was 70 years (range: 41 to 91 years), 47% had Rai stage III or IV disease, 14% had 17p deletion or TP53 mutation, 63% of individuals had an unmutated IGVH, and 18% had 11q deletion. Baseline demographic and disease characteristics were similar between treatment arms.

Efficacy was based on progression-free survival (PFS) as assessed by an Independent Review Committee (IRC). The median duration of follow-up was 28.3 months (range: 0.0 to 40.8 months). With a median follow-up of 28.3 months, median overall survival was not reached in any Calquence arm, with fewer than 10% of individuals experiencing an event.

ASCEND

The efficacy of Calquence in individuals with relapsed or refractory CLL was based upon a multicenter, randomized, open-label trial. The trial enrolled 310 individuals with relapsed or refractory CLL after at least 1 prior systemic therapy. The trial excluded individuals with transformed disease, prolymphocytic leukemia, or previous treatment with venetoclax, a Bruton tyrosine kinase inhibitor, or a phosphoinositide-3 kinase inhibitor.

Individuals were randomized in a 1:1 ratio to receive either:

- Calquence 100 mg approximately every 12 hours until disease progression or unacceptable toxicity, or
- Investigator's choice:
    - Idelalisib plus a rituximab product (IR)
    - Bendamustine plus a rituximab product (BR)

Randomization was stratified by 17p deletion mutation status, ECOG performance status (0 or 1 versus 2), and number of prior therapies (1 to 3 versus ≥ 4). Of 310 individuals total, 155 were assigned to Calquence monotherapy, 119 to IR, and 36 to BR. The median age overall was 67 years (range: 32 to 90 years), 42% had Rai stage III or IV disease, 28% had 17p deletion or TP53 mutation, 78% of individuals had an unmutated IGVH, and 27% had a 11q deletion. The Calquence arm had a median of 1 prior therapy (range 1-8), with 47% having at least 2 prior therapies. The investigator's choice arm had a median of 2 prior therapies (range 1-10), with 57% having at least 2 prior therapies.

In the Calquence arm, the median treatment duration was 15.7 months, with 94% of individuals treated for at least 6 months and 86% of individuals treated for at least 1 year. In the

investigator's choice arm, the median treatment duration was 8.4 months, with 59% of individuals treated for at least 6 months and 37% treated for at least 1 year.

Efficacy was based on PFS as assessed by an IRC, with a median follow-up of 16.1 months (range 0.03 to 22.4 months). There was no statistically significant difference in overall response rates between the two treatment arms. With a median follow up of 16.1 months, median overall survival was not reached in either arm, with fewer than 11% of individuals experiencing an event.

Imbruvica (ibrutinib)

Imbruvica (ibrutinib) was the first inhibitor of Bruton's Tyrosine Kinase (BTK) that is used to treat Mantle Cell Lymphoma. Individuals (n = 111) with confirmed relapsed or refractory mantle cell lymphoma (MCL) who had undergone at least 1, but no more than 5, prior treatment regimens were studied. These subjects were classified as either having been treated with bortezomib therapy (≥ 2 cycles) or not (< 2 complete cycles or no prior bortezomib therapy). The primary efficacy outcome was overall response rate (complete plus partial responses). Overall response rate (ORR) for all individuals was 68%, with 48.6% of individuals having a partial response and 17.1% having complete response (CR). Response to therapy did not differ by baseline characteristics or presence of risk factors associated with chemotherapy treatment failure.

Response rates were similar regardless of prior bortezomib therapy; 63% (17 of 27) individuals previously treated with lenalidomide had a response to ibrutinib. For the 75 individuals having a response at the time of data analysis, the estimated median response duration was 17.5 months (range: 0.0 to 19.6; 95% CI: 15.8, not reached). Median overall survival (OS) for this study was not reached (estimated OS of 58% at 18 months).

Approval for chronic lymphocytic leukemia was based on one small open label trial of 48 previously treated individuals with baseline ECOG scores of 0-1. Individuals received ibrutinib 420mg per day. Median number of prior treatments was 4. ORR was 58.3%, all partial responses.

The safety and efficacy of Imbruvica in MZL were evaluated in an open-label, multi-center, single-arm trial of individuals who received at least one prior therapy. The efficacy analysis included 63 individuals with 3 sub-types of MZL: mucosa-associated lymphoid tissue (MALT; N=32), nodal (N=17); and splenic (N=14). The median age was 66 years (range, 30 to 92 years), 59% were female, and 84% were Caucasian. Ninety-two percent of individuals had a baseline ECOG performance status of 0 or 1 and 8% had ECOG performance status 2. The median time since diagnosis was 3.8 years, and the median number of prior treatments was 2 (range, 1 to 9 treatments).

Brukinsa (zanubrutinib)

Mantle Cell Lymphoma (MCL)

The efficacy of Brukinsa was assessed in BGB-3111-206, a Phase 2, open-label, multicenter, single-arm trial of 86 previously treated individuals with mantle cell lymphoma (MCL) who had received at least one prior therapy. Brukinsa was given orally at a dose of 160 mg twice daily until disease progression or unacceptable toxicity.

The median age of individuals was 60.5 years (range: 34 to 75) and the majority were male (78%). The median time since diagnosis to study entry was 30 months (range: 3 to 102) and the median number of prior therapies was 2 (range: 1 to 4). The most common prior regimens were CHOP-based (91%) followed by rituximab-based (74%). The majority of individuals had extranodal involvement (71%) and refractory disease (52%). Blastoid variant of MCL was present in 14% of individuals. The MIPI score was low in 58%, intermediate in 29%, and high risk in 13%. The overall response rate (ORR) in Study BGB-3111-206 was 84% (95% CI = 74% to 91%)

The efficacy of Brukinsa was also assessed in BGB-3111-AU-003, a Phase 1/2, open-label, dose-escalation, global, multicenter, single-arm trial of B-cell malignancies including 32 previously treated MCL individuals treated with Brukinsa. Brukinsa was given orally at doses of 160 mg twice daily or 320 mg daily. The median age of individuals with previously treated MCL was 70 years (range: 42 to 86), and 38% of individuals were ≥ 75 years old. Most individuals were male (69%) and Caucasian (78%). The MIPI score was low in 28%, intermediate in 41%, and high risk in 31%. The ORR in Study BGB-3111-AU-003 was 84% (95% CI = 67% to 95%).

Waldenström's Macroglobulinemia (WM)

The efficacy of Brukinsa was evaluated in ASPEN [NCT03053440], a randomized, active control, open-label trial, comparing Brukinsa and ibrutinib in individuals with MYD88 L265P mutation ($MYD88^{MUT}$) WM. Individuals in Cohort 1 (n=201) were randomized 1:1 to receive Brukinsa 160 mg twice daily or ibrutinib 420 mg once daily until disease progression or unacceptable toxicity. Randomization was stratified by number of prior therapies (0 versus 1-3 versus > 3) and CXCR4 status (presence or absence of a WHIM-like mutation as measured by Sanger assay).

The major efficacy outcome was the response rate defined as partial response (PR) or better as assessed by Independent Review Committee (IRC) based on standard consensus response

criteria from the International Workshop on Waldenström's Macroglobulinemia (IWWM)-6 criteria. An additional efficacy outcome measure was duration of response (DOR).

The median age was 70 years (range: 38 to 90) and 68% were male. Of those enrolled, 2% were Asian, 91% were White and 7% were of unknown race. ECOG performance status of 0 or 1 was present in 93% individuals at baseline and 7% had a baseline ECOG performance status of 2. A total of 82% had relapsed/refractory disease with 85% having received prior alkylating agents and 91% prior anti-CD20 therapy. The median number of prior therapies in those with relapsed/refractory disease was 1 (range: 1 to 8). A total of 91 (45%) individuals had International Prognostic Scoring System (IPSS) high WM.

The study did not meet statistical significance for the pre-specified efficacy outcome of superior complete response (CR) + very good partial response (VGPR) as assessed by IRC, tested first in individuals with R/R disease in ASPEN.

Cohort 2 enrolled individuals with MYD88 wildtype ($MYD88^{WT}$) or MYD88 mutation unknown WM (N = 26 and 2, respectively) and received Brukinsa 160 mg twice daily. The median age was 72 years (range: 39 to 87) with 43% > 75 years, 50% were male, 96% were White and 4% were not reported (unknown race). 86% individuals had a baseline ECOG performance status 0 or 1 and 14% had a baseline performance status of 2. Twenty-three of the 28 individuals in Cohort 2 had relapsed or refractory disease.

In Cohort 2, response (CR+VGPR+PR) as assessed by IRC using IWWM-6 or modified IWWM-6 was seen in 50% (13 out of 26 response evaluable individuals; 95% CI: 29.9, 70.1).

Marginal Zone Lymphoma (MZL)

The efficacy of Brukinsa was assessed in Study BGB-3111-214 [NCT03846427], an open-label, multicenter, single-arm trial that evaluated 66 individuals with MZL who received at least one prior anti-CD20-based therapy. Brukinsa was given orally at a dosage of 160 mg twice daily until disease progression or unacceptable toxicity. The median age was 70 years (range: 37 to 85); 55% were male; 38% had extranodal MZL, 38% nodal, 18% splenic and 6% had unknown subtype. The median number of prior systemic therapies was 2 (range: 1 to 6), with 27% having 3 or more lines of systemic therapy; 88% had prior rituximab-based chemotherapy; 32% had refractory disease at study entry.

The efficacy of Brukinsa was also assessed in BGB-3111-AU-003 [NCT02343120], an open-label, multicenter, single-arm trial that included 20 individuals with previously treated MZL (45% having extranodal MZL, 25% nodal, 30% splenic). Brukinsa was given orally at dosages of 160

mg twice daily or 320 mg once daily. The median age was 70 years (range: 52 to 85); 50% were male. The median number of prior systemic therapies was 2 (range: 1 to 5), with 20% having 3 or more lines of systemic therapy; 95% had prior rituximab-based chemotherapy.

Efficacy was based on overall response rate (ORR) and duration of response as assessed by an Independent Review Committee (IRC) using 2014 Lugano criteria. In study BGB-3111-214, ORR prioritizing PET-CT when available (55 individuals, with the remainder assessed by CT scan) was 67% (95% CI: 54, 78) with a CR rate of 26%.

2019 Update

Reviewed prescribing information for all drugs in policy. Added a new indication identified for Calquence (acalabrutinib) for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). No additional evidence was identified that would require changes to other drugs listed in this policy.

2020 Update

Reviewed prescribing information for all drugs in policy. No new information was identified that would require changes to this policy.

2021 Update

Reviewed prescribing information for all drugs in policy. Added two new indications identified for Brukinsa (zanubrutinib) which are for the treatment of Waldenström's macroglobulinemia (WM) and for the treatment of relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

2022 Update

Reviewed prescribing information for all drugs in policy. No new information was identified that would require changes to this policy.

2023 Update

Reviewed prescribing information for all drugs in policy. Removed Imbruvica's indications of Mantle Cell Lymphoma and Marginal Zone Lymphoma to match with FDA label changes.

2024 Update

Reviewed prescribing information for all drugs in policy. Updated Jaypirca (pirtobrutinib) with coverage criteria for the treatment of certain individuals with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Updated Imbruvica (ibrutinib) coverage criteria to limit use to adults. Updated age requirement for Imbruvica (ibrutinib) chronic graft versus host disease coverage criteria from 18 years of age or older to 1 year of age or older. Updated Brukinsa (zanubrutinib) coverage criteria to include treatment of certain individuals with follicular lymphoma.

2025 Update

Reviewed prescribing information for all drugs in policy. Added a new indication to Calquence (acalabrutinib) for the treatment of adults with previously untreated mantle cell lymphoma. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

References

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4. American Cancer Society. Cancer Facts & Figures 2025. Atlanta: American Cancer Society; 2025. Available at: **https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2025-cancer-facts-figures.html**. Accessed January 29, 2025.

5. Imbruvica Prescribing Information. Pharmacyclics LLC, Sunnyvale, CA. Revised February 2024.
6. Calquence Prescribing Information. AstraZeneca Pharmaceuticals, Wilmington, DE. Revised January 2025.
7. Brukinsa Prescribing Information. BeiGene USA, Inc., San Mateo, CA. Revised March 2024.
8. Jaypirca Prescribing Information. Lilly USA, LLC, Indianapolis, IN. Revised June 2024.

History

Date	Comments
11/01/18	New policy, approved October 9, 2018. Add to Prescription Drug section. Transferred Ibrutinib and Acalabrutinib from policy 5.10.534. Updated indications per labels.
01/01/20	Annual Review, approved December 10, 2019. Updated criteria for Calquence (acalabrutinib).
04/01/20	Interim Review, approved March 10, 2020. Added criteria for Brukinsa (zanubrutinib) for the treatment of MCL.
12/01/20	Annual Review, approved November 3, 2020. No changes to policy statements.
11/01/21	Annual Review, approved October 5, 2021. Updated Brukinsa (zanubrutinib) criteria adding coverage for the treatment of Waldenström's macroglobulinemia and for the treatment of marginal zone lymphoma.
01/01/23	Annual Review, approved December 23, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
03/01/23	Interim Review, approved February 14, 2023. Added coverage for Jaypirca (pirtobrutinib) for the treatment of relapsed or refractory MCL. Added a new indication to Brukinsa (zanubrutinib) for the treatment of adults with CLL or SLL.
07/01/23	Annual Review, approved June 13, 2023. Reviewed prescribing information for all drugs in policy. Removed Imbruvica's indications of Mantle Cell Lymphoma and Marginal Zone Lymphoma to match with FDA label changes.
04/01/24	Annual Review, approved March 12, 2024. Updated Jaypirca (pirtobrutinib) with coverage criteria for the treatment of certain individuals with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Updated Imbruvica (ibrutinib) coverage criteria to limit use to adults.
06/01/24	Interim Review, approved May 14, 2024. Updated age requirement for Imbruvica (ibrutinib) chronic graft versus host disease coverage criteria from 18 years of age or older to 1 year of age or older. Updated Brukinsa (zanubrutinib) coverage criteria to include treatment of certain individuals with follicular lymphoma.
03/01/25	Annual Review, approved February 11, 2025. Added a new indication to Calquence (acalabrutinib) for the treatment of adults with previously untreated mantle cell

Date	Comments
	lymphoma. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.