Clinical Policy: Olaparib (Lynparza)

Reference Number: CP.PHAR.360
Effective Date: 10.03.17
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Olaparib (Lynparza®) is a poly (ADP-ribose) polymerase (PARP) inhibitor.

FDA Approved Indication(s)

Lynparza is indicated for:

- Maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza
- Use in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability
- Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy
- Treatment of patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER-2)- negative high risk metastatic

breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Lynparza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all)**:**

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For brand Lynparza requests, member must use generic olaparib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. One of the following (a, b, c, or d):
   a. All of the following (i, ii, and iii):
      i. Documentation of a deleterious or suspected deleterious germline BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);
      ii. Failure of ≥ 3 lines of platinum-based chemotherapy (*see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated;
      iii. Provider attestation of acknowledgement for withdrawal of FDA-approved indication for the treatment of adults with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy due to risk of potential detrimental effect on overall survival (OS) in patients who used Lynparza;
   b. Completed ≥ 2 platinum-based chemotherapy regimens and is in a complete or partial response;
   c. Both i and ii:
      i. Documentation of a deleterious or suspected deleterious germline or somatic BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);
      ii. Completed a platinum-based chemotherapy regimen and is in a complete or partial response;
   d. Both i and ii:
      i. Disease is associated with HRD-positive status defined by one of the following (1 or 2):
         1) Documentation of a deleterious or suspected deleterious BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);
         2) Documentation of genomic instability;

ii. Both of the following (1 and 2):
1) Completed a bevacizumab- and platinum-based chemotherapy regimen as first-line therapy, and is in a complete or partial response (*see Appendix B*);
2) Lynparza is prescribed in combination with bevacizumab;

6. Member has not previously received a PARP inhibitor (e.g., Rubraca®, Talzenna®, Zejula®);
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 600 mg (4 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

B. Breast Cancer (must meet all)**:**
1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For brand Lynparza requests, member must use generic olaparib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Disease has all of the following characteristics (a, b, and c):
   a. HER2-negative;
   b. Deleterious germline BRCA 1/2 mutations as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);
   c. High risk, metastatic or recurrent;
6. Member has not previously received a PARP inhibitor (e.g., Rubraca®, Talzenna®, Zejula®);
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 600 mg (4 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

C. Pancreatic Adenocarcinoma (must meet all)**:**
1. Diagnosis of pancreatic adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For brand Lynparza requests, member must use generic olaparib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Documentation of deleterious or suspected deleterious germline BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);

6. Received > 16 weeks of platinum-based chemotherapy with no disease progression;
7. Member has not previously received a PARP inhibitor (e.g., Rubraca®, Talzenna®, Zejula®);
8. Request meets one of the following (a or b):*
   a. Dose does not exceed 600 mg (4 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

D. Prostate Cancer (must meet all):
1. Diagnosis of metastatic castration-resistant prostate cancer;
2. Documentation of disease progression despite bilateral orchiectomy or other androgen deprivation therapy (ADT) (*see Appendix D*);
3. Documentation of a deleterious or suspected deleterious germline or somatic HRR gene mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx);
4. Member does not have a *PPP2R2A* gene mutation;
5. Prescribed by or in consultation with an oncologist or urologist;
6. Age ≥ 18 years;
7. For brand Lynparza requests, member must use generic olaparib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy;
9. Failure of abiraterone (Zytiga®) or Xtandi® (enzalutamide), unless clinically significant adverse effects are experienced or both are contraindicated;
10. Member has not previously received a PARP inhibitor (e.g., Rubraca®, Talzenna®, Zejula®);
11. Request meets one of the following (a or b):*
    a. Dose does not exceed 600 mg (4 tablets) per day;
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 12 months or duration of request, whichever is less

E. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. If request is for use in an adult member with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with 3 or more prior lines of chemotherapy, provider attestation of acknowledgement for withdrawal of this indication due to risk of potential detrimental effect on OS in patients who used Lynparza;
2. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Lynparza for a covered indication and has received this medication for at least 30 days;
3. Member is responding positively to therapy;
4. For brand Lynparza requests, member must use generic olaparib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. For HRD-positive ovarian cancer within the first 15 months of combination therapy with bevacizumab: Documentation of continued bevacizumab therapy, unless contraindications or clinically significant adverse effects to bevacizumab have developed;
6. For adjuvant therapy in breast cancer, total duration of therapy does not exceed 1 year;
7. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 600 mg (4 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADP: adenosine diphosphate
ADT: androgen deprivation therapy
AML: acute myeloid leukemia
BRCA: breast cancer gene
FDA: Food and Drug Administration
gBRCAm: mutations in the germline BRCA genes
GnRH: gonadotropin-releasing hormone
HER: human epidermal growth factor receptor 2
HR: hormone receptor
HRD: homologous recombination deficiency
HRR: homologous recombination repair
LHRH: luteinizing hormone-releasing hormone
mCRPC: metastatic castration-resistant prostate cancer
MDS: myelodysplastic syndrome
NCCN: National Comprehensive Cancer Network
OS: overall survival
PARP: poly (ADP-ribose) polymerase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ovarian Cancer		
Alimta® (pemetrexed)	Various	Varies
Alkeran® (melphalan)	Various	Varies
Avastin® (bevacizumab)	Various	Varies
carboplatin (Paraplatin®)	Various	Varies
cisplatin (Platinol-AQ®)	Various	Varies
cyclophosphamide (Cytoxan®)	Various	Varies
docetaxel (Taxotere®)	Various	Varies
doxorubicin (Doxil®, Adriamycin®)	Various	Varies
etoposide (Vepesid®)	Various	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine (Gemzar®)	Various	Varies
ifosfamide (Ifex®)	Various	Varies
irinotecan (Camptosar®)	Various	Varies
oxaliplatin (Eloxatin®)	Various	Varies
topotecan (Hycamtin®)	Various	Varies
Hexalen® (altretamine)	Various	Varies
Pancreatic Adenocarcinoma		
FOLFIRINOX (leucovorin, fluorouracil, irinotecan, oxaliplatin)	Various	Varies
gemcitabine + cisplatin	Various	Varies
Prostate Cancer		
abiraterone (Zytiga®) + prednisone	Abiraterone 1,000 mg PO QD + prednisone 5 mg PO BID	Abiraterone 1,000 mg/day + prednisone 10 mg/day
Xtandi® (enzalutamide)	Xtandi 160 mg PO QD	160 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) have been confirmed in patients treated with Lynparza. The majority of the cases (17 of 22) were fatal. If MDS/AML is confirmed, discontinue Lynparza.
- The FDA approved Lynparza with a genetic test called BRACAnalysis CDx, a companion diagnostic that will detect the presence of gBRCAm in blood samples from patients with ovarian cancer. Additional information is available at http://www.fda.gov/companiondiagnostics.
- Lynparza is not indicated for patients with mCRPC with a *PPP2R2A* mutation due to an unfavorable risk-benefit profile for this mutation.
- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL). Per NCCN guidelines for the treatment of prostate cancer, ADT should be continued in the setting of CRPC while additional therapies are applied.
- Examples of ADT include:
  - Bilateral orchiectomy (surgical castration)
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an anti-androgen:
    - LHRH (or GnRH) agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)

        - Anti-androgens: bicalutamide (Casodex®), flutamide, nilutamide (Nilandron®), Xtandi (enzalutamide), Erleada® (apalutamide)
    - LHRH antagonist: Firmagon® (degarelix), Orgovyx® (relugolix)
- There is insufficient data regarding the use of consecutive PARP inhibitors. Most PARP inhibitor pivotal trials excluded prior PARP inhibitor use, the NCCN does not make any explicit recommendations (other than for ovarian cancer, where they state data is limited), and there are no randomized controlled trials evaluating such use.

Appendix E: Withdrawal of 4th-line gBRCAm Advanced Ovarian Cancer Indication

- AstraZeneca Pharmaceuticals LP, manufacturer of Lynparza, voluntarily withdrew Lynparza's FDA-approved indication for treatment of adult patients with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy after a post-market subgroup analysis indicated potential detrimental effect on OS in patients who used Lynparza.
- This withdrawal is based on a recent subgroup analysis that indicated a potential detrimental effect on OS for Lynparza compared to the chemotherapy control arm in the subgroup of patients who had received three or more prior lines of chemotherapy corresponding to the current scope of the treatment indication for Lynparza in the randomized Phase 3 study, SOLO3 (NCT02282020).
    - SOLO3 was requested by the FDA to confirm the clinical benefit of Lynparza in the above indication.
    - SOLO3 is a Phase 3, open-label, randomized, controlled, multi-center study to assess the efficacy and safety of a single agent Lynparza vs. standard of care, based on physician's choice of single agent chemotherapy.
    - The final OS analysis occurred in 2021 and there was an imbalance in favor of the control arm for the subgroup of patients treated with 3 or more prior lines of chemotherapy (HR: 1.33).
    - The final OS results were not statistically significant for the subgroup of patients treated with 2 or more prior lines of chemotherapy [1.07 (0.76, 1.49)] or for the subgroup of patients treated with 3 or more prior lines of chemotherapy [1.33 (0.84, 2.18)].
- Physicians should not initiate new treatment with Lynparza in the treatment indication of adult patients with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Physicians who are currently treating patients with Lynparza for this indication should share this information with their patients so that they can both make an informed decision about their ongoing care.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast, ovarian, pancreatic, prostate cancers	300 mg PO BID	600 mg/day

VI. Product Availability

Tablets: 100 mg, 150 mg

VII. References

1. Lynparza Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP. August 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208558s026lbl.pdf. Accessed September 20, 2022.
2. Olaparib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 15, 2022.
3. National Comprehensive Cancer Network. Breast Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 1, 2021.
4. National Comprehensive Cancer Network. Ovarian Cancer Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed September 14, 2022.
5. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed October 4, 2021.
6. National Comprehensive Cancer Network. Prostate Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 4, 2021.
7. AstraZeneca Plans to Withdraw an Olaparib Indication for Ovarian Cancer. Association of Community Cancer Centers. Available at: https://www.accc-cancer.org/home/news-media/newsfeed/oncology-newsfeed-template/astrazeneca-plans-to-withdraw-an-olaparib-ovarian-cancer-indication. Accessed September 20, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Add new indication for treatment of gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer.	02.20.18	05.18
4Q 2018 annual review: breast cancer: added NCCN off-label uses and summarized NCCN and FDA-approved uses for improved clarity; all indications: removed language "as detected by an FDA approved test"; references reviewed and updated.	07.05.18	11.18
1Q 2019 annual review: Criteria added for new FDA indication for 1st-line maintenance treatment of gBRCAm or sBRCAm advanced ovarian cancer; removed capsule formulation from policy since it has been discontinued; references reviewed and updated.	01.22.19	02.19
RT4: updated FDA indication for maintenance treatment of ovarian cancer from "Select patients with gBRCAm advanced epithelial ovarian, fallopian tube or primary peritoneal cancer for therapy based on an FDA-approved companion diagnostic for Lynparza" to "Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza" per updated verbiage in PI; no change to criteria.	07.09.19	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review and RT4: added new FDA indication and NCCN Compendium supported use in pancreatic adenocarcinoma; references reviewed and updated.	10.30.19	02.20
Criteria added for two newly FDA-approved indications: 1) HRD-positive ovarian cancers in combination with bevacizumab after bevacizumab primary therapy, and 2) HRR-mutated mCRPC; for all indications, added requirement for no prior PARP inhibitor use.	06.02.20	08.20
1Q 2021 annual review: added new template language regarding redirection to generic if available for oral oncology agents; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.15.20	02.21
1Q 2022 annual review: added that mutation analysis must be confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx); added in continued therapy section that total treatment duration as adjuvant therapy in breast cancer does not exceed 1 year; references reviewed and updated.	10.04.21	02.22
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	01.20.22	05.22
RT4: added newly FDA-approved indication: For the adjuvant treatment of HER-2 negative, high risk metastatic breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.	05.13.22	
RT4: due to withdrawal of the previously FDA-approved indication, added prescriber attestation requirement for use in gBRCAm ovarian cancer after ≥ 3 lines of chemotherapy; added information about the withdrawal in Appendix E. Template changes applied to other diagnoses/indications.	09.20.22	

Important Reminders

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.