Clinical Policy: Cardiovascular Agents: Lipotropics

Reference Number: OH.PHAR.PPA.31
Effective Date: 10/19
Last Review Date: 06.22
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description:

CARDIOVASCULAR AGENTS: LIPOTROPICS - ATP Citrate Lyase (ACL) Inhibitor

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NEXLETOL™ (bempedoic acid) NEXLIZET™ (bempedoic acid and ezetimibe tablet)

CARDIOVASCULAR AGENTS: LIPOTROPICS – BILE ACID SEQUESTRANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CHOLESTYRAMINE LIGHT POWDER (generic of Questran Light®) CHOLESTYRAMINE POWDER (generic of Questran) COLESTIPOL tablets (generic of Colestid® tablets) PREVALITE® POWDER (cholestyramine)	COLESTIPOL granules (generic of Colestid® granules) WELCHOL® packets (colesevelam) WELCHOL® tablets (colesevelam)

CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATORVASTATIN (generic of Lipitor®) LOVASTATIN (generic of Mevacor®) PRAVASTATIN (generic of Pravachol®) ROSUVASTATIN (generic of Crestor®) SIMVASTATIN (generic of Zocor®)	ALTOPREV® (lovastatin) EZALLOR™ SPRINKLE (rosuvastatin) FLUVASTATIN (generic of Lescol®, Lescol XL®) LIVALO® (pitavastatin) ZYPITAMAG™ (pitavastatin)

CARDIOVASCULAR AGENTS: LIPOTROPICS - FIBRIC ACID DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
GEMFIBROZIL (generic of Lopid®) FENOFIBRATE TABLETS (generic of Tricor®)	ANTARA® (fenofibrate micronized capsules) FENOFIBRATE CAPSULES (generic of Lipofen®) FENOFIBRIC ACID TABLETS (generic of Fibricor) FENOFIBRIC ACID CAPSULES (generic of Trilipix®) LOFIBRA® (fenofibrate micronized capsules) TRIGLIDE® (fenofibrate tablets)

CARDIOVASCULAR AGENTS: LIPOTROPICS - NICOTINIC ACID DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NIACIN NIASPAN® (niacin) Niacin OTC & Niacin ER OTC	NIACIN ER tablet

CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OMEGA 3-ACID ETHYL ESTERS (generic of Lovaza®)	VASCEPA® (icosapent ethyl)

CARDIOVASCULAR AGENTS: LIPOTROPICS - SELECTIVE CHOLESTEROL ABSORPTION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EZETIMIBE (generic of ZETIA)	SIMVASTATIN/EZETIMIBE (generic for Vytorin®)

CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Inability to utilize agents separately	AMLODIPINE/ATORVASTATIN (generic of Caduet®)

CARDIOVASCULAR AGENTS: LIPOTROPICS - PCSK9 INHIBITORS*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PRALUENT® (alirocumab) REPATHA™ (evolocumab)	

CARDIOVASCULAR AGENTS: LIPOTROPICS - (MTP) inhibitor

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	Juxtapid (Lomitapide)

FDA Approved Indication(s)

Lipotropic agents are indicated for the treatment of:

- angina
- atherosclerosis
- heterozygous familial hypercholesterolemia
- homozygous familial hypercholesterolemia
- hypercholesterolemia
- hyperlipoproteinemia
- hypertension
- hypertriglyceridemia
- myocardial infarction prophylaxis
- pruritus
- reduction of cardiovascular mortality
- stroke prophylaxis
- type 2 diabetes mellitus

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 Buckeye Health Plan, an affiliate of Centene Corporation®, that Colestid granules, Welchol, Altoprev, Ezallor, Lescol, Lescol XL, Livalo, Zypitamag, Antara, Lipofen, Trilipix, Lofibra, Triglide, Niacin ER, Lovaza, Vascepa, Vytorin, Caduet, Praluent, Repatha and Juxtapid **are medically necessary when the following criteria are met:**

I. Initial Approval Criteria

A. Bile Acid Sequestrants:

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug;
4. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication that is preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.
5. For **Welchol** requests, may approve as first-line therapy if member meets one of the following (a or b):
   a. Documentation that the member has a diagnosis of diabetes;
   b. History of an oral hypoglycemic or insulin in the previous 120 days

Approval duration: 12 months.

B. HMG-CoA Reductase Inhibitors (Statins) (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug;
4. Documentation that there have been therapeutic failures to trials of no less than 30 days each of at least two medications that are preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
     NOTE: Pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval duration: 12 months.

C. Fibric Acid Derivatives (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug;
4. Documentation that there has been a therapeutic failure to no less than a 90 day trial of at least one medication that is preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 12 months.

D. Nicotinic Acid Derivatives (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug;
4. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication that is preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 12 months.

E. Omega-3 Fatty Acids (must meet all)**:**

1. Diagnosis of Hypertriglyceridemia;
2. Age ≥ 18 years;
3. Documentation that there has been a therapeutic failure to no less than a 30-day trial of at least one medication that is preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications that are preferred.
   - Contraindication to or drug-to-drug interaction with medications that are preferred.
   - History of unacceptable/toxic side effects to medications that are preferred.

4. Dose does not exceed 4 grams per day.

Approval Duration: 12 months

F. Vytorin (Ezetimibe/Simvastatin) (must meet all)**:**

1. Diagnosis of Hypercholesterolemia, Hyperlipoproteinemia, Homozygous Familial Hypercholesterolemia, Heterozygous Familial Hypercholesterolemia, or Atherosclerotic Cardiovascular Disease;
2. Age≥10 years;
3. Documentation that there has been a therapeutic failure to no less than a 30 day trial of at least one medication that is preferred and within the same class UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications not requiring prior approval.
   - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
   - History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 12 months.

G. Caduet (Amlodipine/Atorvastatin) (must meet all)**:-**

1. Age ≥ 10 years;
2. Medical justification by physician for inability to use separate agents: atorvastatin and amlodipine;
3. Request does not exceed amlodipine 10 mg/atorvastatin 80 mg per day.

Approval Duration: 12 months.

H. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors (must meet ONE of the following [1, 2, OR 3])**:**

1. Diagnosis of **Homozygous Familial Hypercholesterolemia (HoFH)** and meets the following criteria:
   a. Prescribed drug is **Repatha** Age ≥ 10 years;
      Prescribed drug is **Praluent** Age ≥ 18 years;
   b. Documented adherence to prescribed lipid lowering medications for previous 90 days;
   c. Submission of baseline lipid laboratory results;
   d. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those< 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia) and have a trial of TWO or more high potency statins (atorvastatin or rosuvastatin).
   e. Dose of **Repatha** does not exceed 420 mg per month OR
      Dose of **Praluent** does not exceed 300 mg per month.

2. Diagnosis of **Heterozygous Familial Hypercholesterolemia (HeFH)** and meets the following criteria:
   a. Prescribed drug is **Repatha** Age ≥ 10 years;
      Prescribed drug is **Praluent** Age ≥ 18 years;
   b. Documented adherence to prescribed lipid lowering medications for previous 90 days;
   c. Submission of baseline lipid laboratory results;

d. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those< 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia), and have a trial of TWO or more high potency statins (atorvastatin or rosuvastatin).
e. Dose of **Repatha** does not exceed 420 mg per month OR
Dose of **Praluent** does not exceed 300 mg per month.

3. Diagnosis of **Clinical Atherosclerotic Cardiovascular Disease** and meets the following criteria:
a. Age ≥ 18 years;
b. Documented adherence to prescribed lipid lowering medications for previous 90 days;
c. Submission of baseline lipid laboratory results;
d. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin; AND
e. Unable to reach goal LDL-C (LDL ≤ 70mg/dL) with maximally tolerated dose of statin and ezetimibe (Zetia) and have a trial of 2 or more high potency statins (atorvastatin or rosuvastatin).
f. Dose of **Repatha** does not exceed 420 mg per month OR
Dose of **Praluent** does not exceed 300 mg per month.

Approval Duration: 12 months.

I. ATP Citrate Lyase (ACL) Inhibitors (must meet all):
1. Age ≥18 years
2. A trial and failure with one PCSK9 inhibitor
3. Documented adherence to prescribed lipid lowering medications for previous 90 days.
4. Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose
a. **If prescribed Nexlizet** (bempedoic acid and ezetimibe tablet) approval requires the trial to be in combination with ezetimibe (Zetia) in addition to the above requirements
5. Baseline lab results are required, and approvals will be limited to 84 days initially and then annually thereafter. Subsequent approvals will require additional levels drawn to assess response to treatment from baseline and/or attestation of clinical stabilization

Approval Duration: 84 days

J. Lomitapide (Juxtapid) (must meet all):
1. Age ≥ 18 years;
2. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
3. At least a 90-day trial AND unable to reach goal LDL-C (LDL ≤ 100mg/dL) with high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor (or a clinical reason that these medications cannot be utilized)
4. Baseline lab results are required, and approvals will be limited to 180 days initially and then annually thereafter. Subsequent approvals will require additional levels drawn to assess response to treatment from baseline and/or attestation of clinical stabilization

Approval Duration: 180 days

K. Other diagnoses/indications:

1. There are no pharmacy and therapeutic committee approved off-label use criteria for the diagnosis;
2. Use is supported by one of the following (a, b, or c):
   a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1 or 2A (*see Appendix D*);

   b. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
      i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
      ii. Adequate representation of the prescribed drug regimen;
      iii. Clinically meaningful outcomes as a result of the drug therapy in question;
      iv. Appropriate experimental design and method to address research questions (*see Appendix E for additional information*);

   c. Micromedex DrugDex® with strength of recommendation Class I, IIa, or IIb (*see Appendix D*);

3. Prescribed by or in consultation with an appropriate specialist for the diagnosis;
4. Failure of an adequate trial of at least two FDA-approved drugs for the indication and/or drugs that are considered the standard of care, when such agents exist for the same indication at maximum indicated doses, unless no such drugs exist, at maximum indicated doses, unless contraindicated or clinically significant adverse effect are experienced;
5. Dosing regimen and duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature.

Approval duration: 12 months.

II. Continued Therapy

A. Omega-3 Fatty Acids (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by:
   a. Subsequent re-authorizations: continued reduction or maintenance in reduction of TG levels from baseline;

Approval Duration: 12 months.

B. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by lab results and lipid profile. (i.e. member has demonstrated a response to treatment from baseline and/or attestation of clinical stabilization)

Approval Duration: 12 months.

C. ATP Citrate Lyase (ACL) Inhibitors (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by lab results and lipid profile. (i.e. member has demonstrated a response to treatment from baseline and/or attestation of clinical stabilization)

Approval Duration: 12 months.

D. Lomitapide (Juxtapid)

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by lab results and lipid profile. (i.e. member has demonstrated a response to treatment from baseline and/or attestation of clinical stabilization)

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

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.PMN.53 for Medicaid or evidence of coverage documents.

Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ASCVD: Atherosclerotic Cardiovascular Disease
CHD: Coronary Heart Disease
FDA: Food and Drug Administration
FH: familial hypercholesterolemia
HeFH: heterozygous familial hypercholesterolemia
HoFH: homozygous familial hypercholesterolemia
LDL-C: low density lipoprotein cholesterol
LDLR: low density lipoprotein receptor
LDLRAP1: low density lipoprotein receptor adaptor protein 1
PCSK9: proprotein convertase subtilisin kexin 9
SAMS: statin-associated muscle symptoms
TIA: transient ischemic attack
WHO: World Health Organization

PA: Prior Authorization

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 for all relevant lines of business and may require prior authorization.

*****See above tables for preferred alternatives***** *Dosing varies by drug product. See FDA approved dosing and administration.*

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

- See package insert; clinical pharmacology or other appropriate clinical reference

V. Dosage and Administration: varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration.

VI. Product Availability: See package insert; clinical pharmacology or other appropriate clinical reference for product availability

VII. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A
Updated non-preferred Fibric Acid Derivatives	03.20	
Under Initial Approval criteria added section I. ATP Citrate Lyase (ACL) Inhibitors and Continued Therapy section C. For ATP Citrate Lyase (ACL) Inhibitors	07.20	
Annual review- *Under Initial approval section F. **removed** statement 4 *Under initial approval section G. removed 1.a-d; removed 2. Re-numbered section G. 1-3 *Under Initial approval section H **Added** e. Total cholesterol and LDL-C >600 mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing *Under initial approval section H.1.g. **added** Dose of Praluent does not exceed 300 mg per month *Under initial approval section H.2.e. **added** Total Cholesterol > 290 mg/dL *Under initial approval section H.3.e. **added** AND *Under initial approval section I **added** 2. A trial and failure with one PCSK9 inhibitor *Under continued therapy section A.2.a. **removed** a. Initial re-authorization: 20% reduction in TG levels from baseline **also removed** 4. If request is for a dose increase, new dose does not exceed 4 g (4 capsules) per day.	6-21	
Revised preferred and non-preferred charts and updated duration of approval for (PCSK9) Inhibitors & ATP Citrate Lyase (ACL) Inhibitors	11.21	

Under initial approval section H. Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) revised age requirements: for both diagnosis (HeFH) and HoFH Repatha Age ≥ 10 years; and Praluent Age ≥ 18 years; *Under initial approval section H.1. removed a, e & f and renumbered section H.1. a-e *Under initial approval H.1. added d. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those< 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia) and have a trial of TWO or more high potency statins (atorvastatin or rosuvastatin). *Under initial approval section H.2. Removed a,e & f and renumbered section H.2. a-e *Under section H.2. added d. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those< 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia), and have a trial of TWO or more high potency statins (atorvastatin or rosuvastatin). *under section H.3. removed a, e & f and renumbered section H.3. a-f *Under section H.3. added e. Unable to reach goal LDL-C (LDL ≤ 70mg/dL) with maximally tolerated dose of statin and ezetimibe (Zetia) and have a trial of 2 or more high potency statins (atorvastatin or rosuvastatin). **Under initial approval section I. ATP Citrate Lyase (ACL) Inhibitors**; Removed number 6 and renumbered this section of criteria 1-4 *under initial approval; revised approval duration to 84 days *Under continued therapy II.B. **For Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9)** revised number 2 to read as follows: 2. Member is responding positively to therapy as evidenced by lab results and lipid profile. Under continued therapy II.C For ATP Citrate Lyase (ACL) Inhibitors revised number 2 to read as follows: 2. Member is responding positively to therapy as evidenced by lab results and lipid profile.	2.22	4.22

Revised section I to be as follows: **I. ATP Citrate Lyase (ACL) Inhibitors (must meet all):** 1. Age ≥18 years 2. A trial and failure with one PCSK9 inhibitor 3. Documented adherence to prescribed lipid lowering medications for previous 90 days. 4. Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose a. If prescribed Nexlizet (bempedoic acid and ezetimibe tablet) approval requires the trial to be in combination with ezetimibe (Zetia) in addition to the above requirements 5. Baseline lab results are required, and approvals will be limited to 84 days initially and then annually thereafter. Subsequent approvals will require additional levels drawn to assess response to treatment from baseline and/or attestation of clinical stabilization Approval Duration: 84 days **Added section J** **J. Lomitapide (Juxtapid) (must meet all):** 1. Age ≥ 18 years; 2. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) 3. At least a 90-day trial AND unable to reach goal LDL-C (LDL ≤ 100mg/dL) with high- potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor (or a clinical reason that these medications cannot be utilized) 4. Baseline lab results are required, and approvals will be limited to 180 days initially and then annually thereafter. Subsequent approvals will require additional levels drawn to assess response to treatment from baseline and/or attestation of clinical stabilization Approval Duration: 180 days **Continued therapy added the following verbiage to section B & C** (i.e. member has demonstrated a response to treatment from baseline and/or attestation of clinical stabilization) Also added section D For Lomitapide (Juxtapid) 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria; 2. Member is responding positively to therapy as evidenced by lab results and lipid profile. (i.e. member has demonstrated a response to treatment from baseline and/or attestation of clinical stabilization)	6.22	7.22

Important Reminder

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.

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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.