Clinical Policy: Testosterone (Injectable; Nasal; Transdermal)

Reference Number: AZ.CP.PMN.02
Effective Date: 11.16.16
Last Review Date: 04.21
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

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

Description
The following are testosterone replacement agents requiring prior authorization: testosterone gel (AndroGel®, Fortesta®, Testim®, Vogelxo®), testosterone transdermal patch (Androderm®), testosterone topical solution, testosterone cypionate oil (Depo-Testosterone®), testosterone enanthate oil, testosterone enanthate (Xyosted®), teststosterone undecanoate (Aveed®), and testosterone nasal gel (Natesto®).

AHCCCS preferred drugs in this class include AndroGel (testosterone gel), Androderm (testosterone transdermal patch), testosterone cypionate oil, and testosterone enanthate oil.

AHCCCS non-preferred drugs in this class include generic Aveed (testosterone undecanoate), Depo-Testosterone (testosterone cypionate oil), Fortesta/Testim/Vogelxo/generic testosterone gel, testosterone topical solution, Natesto (testosterone nasal gel), and Xyosted (testosterone enanthate).

FDA approved indication
- Testosterone is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone
- Testosterone enanthate oil is indicated for palliation of inoperable metastatic (skeletal) mammary cancer in women who are 1 to 5 years postmenopausal
- Testosterone enanthate oil is indicated for treatment of delayed puberty in carefully selected males

Limitation of use:
- The safety and efficacy of (testosterone therapy) has not been established in men with late-onset (age-related) hypogonadism.
- Topical testosterone products may have different strengths or application instructions that may result in different systemic exposure.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

CLINICAL POLICY
Testosterone (Injectable; Nasal; Transdermal)

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Androderm, Aveed, Nastesto, testosterone cypionate oil, testosterone enanthate oil, testosterone gel, testosterone topical solution, and Xyosted are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Testosterone Replacement Therapy (must meet all)**:**

1. Diagnosis of Primary Hypogonadism or Hypogonadotropic Hypogonadism;
2. Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days within the last 6 months;
3. If request is for brand name drug with an existing FDA approved generic equivalent (e.g., Depo-Testosterone, Fortesta, Vogelxo, Testim): Refer to AZ.CP.PMN.16 Non-Preferred Drugs and Brand name Override;
4. For generic testosterone gel or testosterone topical solution requests: failure of brand name AndroGel AND Androderm at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. For Aveed, Natesto, or Xyosted requests: failure of testosterone cypionate or testosterone enanthate in oil AND a topical preparation of testosterone (e.g., AndroGel, Androderm) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Member is not also taking an aromatase inhibitor (e.g., Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane]);
7. Dose does not exceed the FDA approved maximum (see Section V).

Approval duration: 12 months

B. Advanced Inoperable Carcinoma of the Breast: (must meet all)**:**

1. Diagnosis of Metastatic Skeletal Mammary Cancer;
2. Request is for testosterone enanthate oil;
3. Prescribed by or in consultation with an oncologist;
4. Member is 1-5 years post-menopausal;
5. Dose does not exceed 400 mg every 2 weeks.

Approval duration: 12 months

C. Delayed Puberty (must meet all)**:**

1. Diagnosis of delayed puberty;
2. Request is for testosterone cypionate or enanthate oil;
3. Prescribed by or in consultation with an endocrinologist;
4. Dose does not exceed 200 mg every 2 weeks.

Approval duration: 6 months

D. Gender Dysphoria (off-label) (must meet all):

1. Diagnosis of Gender Dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5);

2. If request is for brand name drug with an existing FDA approved generic equivalent (e.g., AndroGel, Depo-Testosterone, Fortesta, Vogelxo, Testim): Refer to AZ.CP.PMN.16 Non-Preferred Drugs and Brand name Override;
3. For generic testosterone gel or testosterone topical solution requests: failure of brand name AndroGel AND Androderm at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. For Aveed, Natesto, or Xyosted requests: failure of testosterone cypionate or testosterone enanthate in oil AND a topical preparation of testosterone (e.g., AndroGel, Androderm) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member is not also taking an aromatase inhibitor (e.g., Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane]);
6. Dose does not exceed general guidelines for the relevant indication (see Section V).

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to AZ.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Testosterone Replacement Therapy (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Documentation of response to therapy and appropriate monitoring of lab values within appropriate therapeutic range for the patient;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum (see Section V).

Approval duration: 12 months

B. Advanced Inoperable Carcinoma of the Breast: (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Member is 1-5 years post-menopausal;
3. If request is for a dose increase, new dose does not exceed 400 mg every 2 weeks.

Approval duration: 12 months

C. Delayed Puberty (must meet all):

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

D. Gender Dysphoria: (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;

2. Documentation of response to therapy and appropriate monitoring of lab values within appropriate therapeutic range for the patient;
3. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to AZ.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – AZ.CP.PMN.53 for Arizona Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
POME: pulmonary oil microembolism

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
testosterone 1% gel (AndroGel®)	Male hypogonadism: Starting dose: 50 mg applied topically QD. Dose may be titrated to a maximum of 100 mg QD based on serum testosterone level.	100 mg/day
testosterone 1.62% gel (AndroGel®)	Male hypogonadism: Starting dose: 40.5 mg applied topically QD. Dose may be titrated to a maximum of 81 mg QD based on serum testosterone level.	81 mg/day
Androderm® transdermal system 2.5/2/4/5 mg per 24 hr (testosterone patch)	Male hypogonadism: Initiate with 1 patch of the 4 mg/day system (not two 2 mg/day systems) applied nightly to an area of dry, clean skin on the upper arms, thighs, back or abdomen. The patch should be worn for 24 hours. Approximately 2 weeks following initiation or any dose change, measure the early morning serum testosterone concentration	6 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	following system application the previous evening. If the serum concentration is outside the target range of 400 to 930 ng/dL, increase the daily dose to 6 mg (i.e., one 4 mg/day and one 2 mg/day system) or decrease the daily dose to 2 mg (i.e., one 2 mg/day system), maintaining nightly application.	
testosterone cypionate injection	Male hypogonadism: 50 to 400 mg IM once every 2 to 4 weeks	400 mg every 2 to 4 weeks
testosterone enanthate injection	Male hypogonadism: 50 to 400 mg IM once every 2 to 4 weeks Males with delayed puberty: 50 to 200 mg every 2 to 4 weeks for a limited duration, for example, 4 to 6 months Metastatic breast cancer, female: 200 to 400 mg IM every 2 to 4 weeks	400 mg every 2 to 4 weeks

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

- Contraindication(s):
  - Men with known carcinoma of the breast or known or suspected carcinoma of the prostate
  - Pregnant or breastfeeding women
  - Testosterone cypionate, testosterone enanthate, Xyosted: hypersensitivity to product or ingredients
  - Xyosted: men with hypogonadal conditions not associated with structural or genetic etiologies
  - Testosterone cypionate: patients with serious cardiac, hepatic or renal disease
- Boxed warning(s):
  - Aveed: risk of serious pulmonary oil microembolism (POME) reactions (urge to cough, dyspnea, throat tightening, chest pain, dizziness, syncope) and potentially life-threatening anaphylaxis
  - Fortesta, Testim, Vogelxo: secondary exposure to testosterone
  - Xyosted: increases in blood pressure

Appendix D: General Information

- Patients with primary hypogonadism usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone and luteinizing hormone) above the normal range. Patients with hypogonadotropic hypogonadism have low serum testosterone concentrations but have gonadotropins in the normal or low range.

- Per the Endocrine Society (2018), the diagnosis of hypogonadism requires unequivocally and consistently low testosterone levels on at least 2 separate mornings. Although the lower limit of normal for testosterone can vary depending on the laboratory used, clinical trials for a number of testosterone agents defined it as < 300 ng/dL. Additionally, the American Urological Association suggests < 300 ng/dL as a reasonable cut-off in support of low testosterone diagnosis (2018).
- According to 2018 Endocrine Society Clinical Practice Guideline for Testosterone Therapy in Men with Hypogonadism, testosterone replacement therapy should aim to raise serum testosterone concentrations into the mid-normal range (350-600 ng/dL).
- Androgens may be used cautiously to stimulate puberty in carefully selected patients with clearly delayed puberty. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support.
- In females, testosterone has been used for the palliative treatment of androgen-responsive, advanced, inoperable metastatic (skeletal) carcinoma of the breast in women who are 1-5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity include adrenalectomy, hypophysectomy, and/or antiestrogen therapy (e.g. tamoxifen). Androgen therapy also has been used in premenopausal women with carcinoma of the breast who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. The decision to use androgen therapy in women with carcinoma of the breast should be made by an oncologist with expertise in the treatment of this carcinoma.
- Axiron (topical testosterone solution) brand name was discontinued by Lilly on 9/5/2019.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Androderm	Male hypogonadism: 4mg patch applied topically QD at night for 24 hours. Dose should be titrated up/down to maintain serum testosterone level within the therapeutic range. Female-to-male transsexual – Gender dysphoria: 2.5 to 7.5 mg per day	6mg per day
AndroGel	1% starting dose: 50 mg testosterone (two 25 mg packets, or one 50 mg packet) applied topically QD Dose may be titrated to 75mg daily followed by 100mg daily based on serum testosterone level. Dose should be titrated to maintain serum testosterone level within therapeutic range. 1.62% • Male hypogonadism: 40.5 mg (2 pump actuations or a single packet) applied topically	100 mg/day

Drug Name	Dosing Regimen	Maximum Dose
	QD. Dose may be titrated to a maximum of 81 mg QD based on serum testosterone level. Dose should be titrated to maintain serum testosterone level within the therapeutic range. • Female-to-male transsexual – Gender dysphoria: 50 to 100 mg topically once daily	
Aveed	Male hypogonadism: The recommended dose is 3 mL (750 mg) injected intramuscularly, followed by 3 mL (750 mg) injected after 4 weeks, then 3 mL (750 mg) injected every 10 weeks thereafter Female-to-male transsexual – Gender dysphoria: 1000 mg IM at 0 and 6 weeks and then every 12 weeks	N/A
Fortesta	Initial, 40 mg (4 pump actuations) applied topically once daily to clean, dry, intact skin of the front and inner thighs in the morning; titrate dose to a minimum of 10 mg (1 pump actuation) or to a maximum of 70 mg (7 pump actuations) based on serum testosterone level.	70 mg/day
Natesto	11 mg (2 pump actuations; 1 actuation per nostril) administered intranasally TID. Discontinue therapy when total testosterone concentration consistently exceeds 1,050 ng/dL. Alternative treatment should be considered if total testosterone concentration is consistently below 300 ng/dL.	33 mg/day
Testim	50 mg (1 tube) applied topically QD to the shoulders and/or upper arms. Dose may be titrated to a maximum of 100 mg QD based on serum testosterone level. Dose should be titrated to maintain serum testosterone in the range of 300-1,000 ng/dL.	100 mg/day
Testosterone cypionate injection	Male hypogonadism: 50 to 400mg IM once every 2 to 4 weeks Female-to-male transsexual – Gender dysphoria: 100 to 200 mg IM every 2 weeks	N/A
Testosterone enanthate injection	Male hypogonadism: 50 to 400mg IM once every 2 to 4 weeks Female-to-male transsexual – Gender dysphoria: 100 to 200 mg IM every 2 weeks	N/A

Drug Name	Dosing Regimen	Maximum Dose
Testosterone topical solution	Starting dose: 60 mg of testosterone (1 pump actuation of 30 mg testosterone to each axilla) applied once daily at the same time each morning. May increase or decrease by 30mg at a time based on serum levels up to 120mg per day.	120 mg per day (4 actuations)
Vogelxo	50 mg (1 tube or 1 packet or 4 pump actuations) applied topically QD at approximately the same time each day to the shoulders and/or upper arms. Dose may be titrated to a maximum of 100 mg QD based on serum testosterone level. Dose should be titrated to maintain serum testosterone in the range of 300-1,000 ng/dL.	100 mg/day
Xyosted	Male hypogonadism: 75 mg SC once weekly in the abdominal region. Avoid IM and IV administration. Female-to-male transsexual – Gender dysphoria: 100 to 200 mg subQ every 2 weeks or 50% of the dose subQ once weekly	Varies based on testosterone concentration.

VI. Product Availability

Drug	Availability
Testosterone transdermal patch (Androderm)	Transdermal Patch, Extended Release: 2mg/24 HR, 4mg/24 HR
Testosterone gel (AndroGel)	Gel packets: 1% [2.5-gm unit-dose packet (containing 25 mg testosterone), 5-gm unit dose packet (containing 50 mg testosterone)]; 1.62% [1.25-gm unit-dose packet (containing 20.25 mg testosterone), 2.5-gm unit-dose packet (containing 40.5 mg testosterone)] Gel pump: 1.62% [88-gm metered-dose pump (dispenses 60 metered actuations with 20.25 mg testosterone in 1.25 gm gel per actuation)
Testosterone topical solution	Solution in metered-dose pump: 30mg testosterone (1.5 mL of solution) per actuation; each 90 mL pump is capable of delivering 60 metered pump actuations
Testosterone gel (Fortesta)	Gel in metered-dose pump: 10 mg testosterone (0.5gm of gel) per actuation; each 60-gm pump is capable of dispensing 120 metered pump actuations

Testosterone gel (Testim)	1% gel in tube: 5 gm (50 mg testosterone)
Testosterone gel (Vogelxo)	Gel in unit-dose tube or packet: 50 mg testosterone in 5 gm of gel Gel in metered-dose pump: 12.5 mg testosterone (1.25 gm of gel) per actuation; each 75-gm pump is capable of dispensing 60 metered pump actuations
Testosterone cypionate in oil injection (various)	100 mg/ml in 10 ml vials, 200 mg/ml in 1ml and 10ml vials
Testosterone enanthate in oil injection (various)	200 mg/mL in 5mL vials
Teststerone undecanoate injection (Aveed)	750 mg/3 mL in 3ml vials
Xyosted (Testosterone enanthate subcutaneous injection)	Autoinjector: 50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL
Testosterone nasal gel (Natesto)	Intranasal gel in metered dose pump: 11 gm dispensed as 60 metered pump actuations. One pump actuation delivers 5.5 mg of testosterone

VII. References

1. Androderm Prescribing Information. Madison, NJ: Allergan USA, Inc.; May 2020. Available at: www.androderm.com. Accessed March 16, 2021.
2. Androgel 1% Prescribing Information. North Chicago, IL: AbbVie Inc.; May 2019, Available at: www.androgel.com. Accessed March 16, 2021.
3. Androgel 1.62% Prescribing Information. North Chicago, IL: AbbVie Inc.; November 2020, Available at: www.androgel.com. Accessed March 16, 2021.
4. Fortesta Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021463s020lbl.pdf; July 2017. Accessed March 17, 2021.
5. Aveed Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; Available at: www.aveedusa.com; March 2020. Accessed March 17, 2021.
6. Depo-Testosterone (testosterone cypionate) Injection Prescribing Information. New York, NY: Pharmacia & Upjohn Pharmaceutical Corp; August 2018. Available at: www.pfizer.com. Accessed March 17, 2021.
7. Natesto Prescribing Information. Englewood, CO: Aytu BioScience, Inc.; October 2016. Available at: www.natesto.com. Accessed March 17, 2021.
8. Testim Prescribing Information. Malvern, PA: Endo Pharmaceuticals, Inc; November 2020. Available at: www.endo.com. Accessed March 17, 2021.
9. Testosterone Enanthate Injection Prescribing Information. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; December 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed March 17, 2021.

10. Testosterone Solution Prescribing Information. Parsippany, NJ: Actavis Pharma, Inc.; February 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7227ab2f-c8ef-4bab-92ab-3092182abcc9. Accessed March 17, 2021.
11. Vogelxo Prescribing Information. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; April 2020. Available at: www.upsher-smith.com. Accessed March 17, 2021.
12. Xyosted Prescribing Information. Ewing, NJ: Antares Pharma Inc,; Available at: www.xyosted.com; November 2019. Accessed March 17, 2021.
13. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency AUA guideline. American Urological Association. Published 2018. Available at: http://www.auanet.org/guidelines/testosterone-deficiency-(2018).
14. Basin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018; 103(5): 1715-1744. Available at: https://academic.oup.com/jcem/article/103/5/1715/4939465.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Annual Review: - Addition of Axiron to criteria - Addition of requirement of lab values confirming diagnosis and proper management for initial and continued therapy approval	06.17	11.17
Annual Review: Addition of additional Limitations of Use from Prescribing Information Modified preferred products to include Androderm and Axiron per AHCCCS Drug List	09.12.18	10.18
Annual Review: Addition of Aveed, Jatenzo, Striant, Natesto, and Xyosted: indication, general information and dosing. Addition of off label Gender Dysphoria indication. Update of references.	08.01.19	9.19
Annual Review: Removed Axiron brand, testosterone enanthate generic as they are no longer manufactured; references updated.	8.01.20	10.20
AHCCCS preferred androgenic agents update effective 4/1/21: brand name AndroGel pump, packet and	3.17.2021	04.21

CLINICAL POLICY
Testosterone (Injectable; Nasal; Transdermal)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Androderm added; Added lists of AHCCCS preferred and non-preferred drugs; Removed Striant due to discontinuation; Removed Jatenzo as it is now referred to CP.PMN.354; Added testosterone enanthate oil; Changed the language for requirement of testosterone lab values from "as evidenced with recent (within past 90 days) lab values below therapeutic range" to "Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days within the last 6 months"; Added indication of Delayed Puberty for injectable testosterone; Added criterion for generic testosterone gel and testosterone topical solution requests as they are non-preferred; Added criterion "Request is for testosterone enanthate oil" for Advanced Inoperable Carcinoma of the Breast indication; Organized previous Appendix B: General Information and is now broken into Appendix B: Therapeutic Alternatives, Appendix C: Contraindications/Boxed Warnings, and Appendix D: General Information; references reviewed and updated.		
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21

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.

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.