PROVIDER*ALERT*

AmeriHealth Caritas Louisiana

To: **AmeriHealth Caritas Louisiana Providers**

Date: **April 11, 2024**

Subject: **LDH Approved Clinical Policies**

Summary: Four LDH Approved Clinical Policies.

AmeriHealth Caritas Louisiana would like to inform you of four new policies that have been approved by the Louisiana Department of Health in accordance with La. R.S. 46:460.54. The guidelines are effective on **May 11, 2024** and will be posted on our website under Clinical Policies: https://www.amerihealthcaritasla.com/provider/resources/clinical/policies.aspx.

1. Chronic Pain Management
2. Microwave Thermotherapy for Lung and Kidney Tumors
3. Opioid Treatment
4. Prostatic Urethral Lift/UroLift for Prostatic Hypertrophy

Reminder: If your practice is not registered with our website portal-NaviNet, we highly recommend registering. To register, please visit www.navinet.net to sign up or contact your Provider Account Executive for details.

Questions: Thank you for your continued support and commitment to the care of our members. If you have questions about this communication, please get in touch with AmeriHealth Caritas Louisiana Provider Services at 1-888-922-0007 or your Provider Network Management Account Executive.

Missed an alert? You can find a complete list of provider alerts on our website's Provider Newsletters and Updates page.

Need to update your provider information? Send full details to network@amerihealthcaritasla.com.

Chronic Pain Management

Plan: AmeriHealth Caritas Louisiana

Clinical Policy ID: CCP.4005

Recent review date: 10/2023

Next review date: 2/2025

Policy contains: Chronic pain.

AmeriHealth Caritas Louisiana has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Louisiana's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Louisiana when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Louisiana's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Louisiana's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Louisiana will update its clinical policies as necessary. AmeriHealth Caritas Louisiana's clinical policies are not guarantees of payment

Policy statement

AmeriHealth Caritas Louisiana covers the epidural injection of an anesthetic substance for the prevention or control of acute pain such as that which occurs during delivery or surgery. Billing of these procedures subsequently for pain management, pain control, or any another reason is not covered. AmeriHealth Caritas Louisiana does not cover spinal injections to alleviate chronic, intractable pain.

Coverage for chronic intractable pain is dependent on the clinical etiology and the type of service or treatment. AmeriHealth Caritas Louisiana's coverage policy shall include the provisions within this section.

If an enrollee requests treatment for chronic intractable pain, depending on the underlying cause or anatomical defect, the provider may determine treatment or management to include physical therapy, occupational therapy, medication therapy management, epidural steroid injection therapy, acupuncture, chiropractic, behavioral health and addiction medicine services in coordination with case management. These include some alternative treatments, and the inclusion of coverage on the Professional Services Fee Schedule will define covered treatments. AmeriHealth Caritas Louisiana may offer additional treatments via authorized in lieu of services or value-added benefits.

Certain Medicaid procedures or services may require prior authorization. CPT codes for the treatment of chronic intractable pain requiring PA can be identified on the Professional Services Fee Schedule. Note: Medical necessity for epidural steroid injection (ESI) shall be determined by the history of illness, physical examination, and concordant diagnostic imaging supporting radiculopathy, radicular pain, or neurogenic claudication due to herniation, stenosis, and/or degenerative disease protracted and severe enough to greatly impact quality of life or

function (Louisiana Medicaid Managed Care Organization Manual, 2023).

Physical medicine and rehabilitation consultations for chronic pain management are services covered by AmeriHealth Caritas Louisiana.

References

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Louisiana Medicaid Professional Services Provider Manual. 2012. Anesthesia. Chapter 5, Section 5.1. https://www.lamedicaid.com/provweb1/providermanuals/manuals/ps/ps.pdf. Issued October 7, 2022.

Policy updates

Initial review date: 3/1/2021

11/2023: Policy references updated.

AmeriHealth Caritas Louisiana

Microwave thermotherapy for lung and kidney tumors

Clinical Policy ID: CCP.1528

Recent review date: 7/2023

Next review date: 10/2024

Policy contains: Image-guided thermal ablation, microwave ablation, non-small cell lung cancer, percutaneous ablation, renal cell carcinoma

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

See also CCP.1397 Microwave thermotherapy for breast cancer.

Microwave thermotherapy (ablation) of a primary or metastatic lung tumor is clinically proven and, therefore, may be medically necessary when all of the following criteria are met (National Comprehensive Cancer Network, 2023b):

- The member either:
  - Is deemed medically inoperable due to the location or extent of the lesion or due to comorbid conditions.
  - Will not receive stereotactic ablative radiotherapy or definitive radiation therapy.
- A single tumor is less than or equal to 3 centimeters in size.

Microwave ablation of malignant kidney tumors is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Findings

Alternative covered services

- Radiofrequency ablation.
- Cryoablation.
- Surgical resection.
- Stereotactic radiosurgery.
- Definitive radiation therapy.

Background

Tumor ablation is a minimally invasive technique that applies chemical or thermal methods under image guidance to induce cellular necrosis and destroy solid tumors while sparing adjacent tissue. Thermal ablation is accomplished by cooling or heating the targeted tissue to less than minus 40 degrees Celsius or more than 60 degrees Celsius, which will achieve cytotoxicity in most tissues. Depending on the technique, targeted tissues may be accessed percutaneously, laparoscopically, intraoperatively, endoscopically, or, in the case of high-intensity focused ultrasound, extracorporeally, to achieve locoregional tumor control (Gala, 2020).

Several minimally invasive thermal ablative modalities are available: radiofrequency, laser, cryoablation, high-intensity focused ultrasound, and microwave. Irreversible electroporation is a nonthermal option that applies short pulses of a strong electrical current to form permanent nanopores within the cell membrane to induce cell death. Radiofrequency is the most commonly used ablative modality for locoregional tumor eradication, but microwave ablation has emerged as an alternative (Gala, 2020).

Microwave systems comprise a microwave generator, a coaxial cable, and a 14 to 17-gauge antenna to transmit the waves to the tissue. Antenna (needle) placement is achieved using ultrasound, computed tomography, or fluoroscopic guidance, depending on lesion location. Total tumor necrosis can be achieved when temperature remains at 54 degrees Celsius for at least three minutes, or reaches 60 degrees Celsius instantly (Gala, 2020).

Both microwave and radiofrequency methods convert heat energy into coagulative necrosis of tumor cells. Unlike radiofrequency ablation, which uses electrical energy at a frequency of 3 hertz to 300 gigahertz, microwave ablation applies short-duration, high-voltage electromagnetic pulses with frequencies between 900 and 2,450 megahertz. Because of its larger electromagnetic field and rapid heating capabilities, microwave ablation creates a larger, homogenous ablative field and avoids the “heat sink” effect that commonly occurs with radiofrequency ablation of highly vascular solid organs. As a result, higher intratumoral temperatures and larger and predictable ablation zones can be created in a shorter time period. In addition, microwave ablation is not limited by the poor electrical conductivity and thermal conduction of charred or desiccated lung tissue, which can reduce the effectiveness of radiofrequency ablation (Gala, 2020).

For assessing response to locoregional treatment, computed tomography and magnetic resonance imaging are used at regular intervals. The optimal imaging modality for follow-up and imaging interpretation will depend on the therapy used and planned future treatments (American College of Radiology, 2018).

The U.S. Food and Drug Administration (2023) has issued 510(k) premarket approval to several microwave ablation devices as electrosurgical cutting and coagulation devices and accessories for soft tissue ablation.

Lung tumors

There is sufficient evidence from professional guidance, systematic reviews and meta-analyses of non-randomized studies, and two randomized studies described below to support the safety and efficacy of microwave ablation for treating malignant lung tumors. The study populations consisted of participants with various stages of primary and secondary lung cancer who were not candidates for surgical resection and were expected to have lower survival. The advantages of image-guided tumor ablation methods compared to surgical treatment are faster recovery, reduced morbidity and mortality, accurate targeting under ultrasound or computed tomography guidance, and outpatient treatments.

Microwave ablation appears to be safe and efficacious in selected patients with primary or secondary lung tumors smaller than 3 centimeters who are not ideal surgical candidates. Serious events are rare, and pneumothorax requiring chest tubes is the most common complication. Microwave ablation is delivered in fewer sessions than radiofrequency ablation, and can achieve similar outcomes with lower morbidity. Estimates of local recurrence are highly variable and may reflect the limitations in the evidence base (e.g., retrospective nature, heterogeneity, and small sample sizes). Prospective comparisons to other therapeutic regimens, radiofrequency ablation in particular, are needed to further clarify the role of microwave ablation in treating non-small cell lung cancer. The effect of microwave ablation combined with chemotherapy regimens also requires further research.

The National Comprehensive Cancer Network (2023b) recommends image-guided thermal ablation (e.g., cryotherapy, microwave ablation, or radiofrequency ablation) for treatment of primary or secondary lung tumors smaller than 3 centimeters for patients who are medically inoperable, refuse surgery, or will not receive stereotactic ablative radiotherapy or definitive radiation therapy. Each energy modality has advantages and disadvantages. The size and location of the target tumor, risk of complications, and local expertise or operator familiarity are factors in determining choice of ablative method.

A prospective trial of 52 participants with inoperable stage 4 disease were randomized to receive either microwave ablation or radiofrequency ablation. Microwave ablation produced less intraprocedural pain ($P = .0043$) and a significant reduction in tumor mass from pre-therapy to 12 months follow-up ($P = .0215$). There were no significant differences in mortality rates or overall survival between groups. Complication rates trended lower in the microwave ablation group (33.33% versus 57.14%, $P = .051$) (Macchi, 2017).

A multisite, randomized controlled trial compared the effectiveness of platinum plus third-generation chemotherapy combined with microwave ablation (n = 148 with 117 tumors) to chemotherapy alone (n = 145 with 113 tumors) for treating stage 3B and 4 non-small cell lung cancer. Baseline characteristics and median follow-up periods were similar between groups. The combined treatment group experienced higher median progression-free survival (10.3 months versus 4.9 months; hazard ratio = 0.44, 95% confidence interval 0.28 to 0.53; $P < .0001$) and higher overall survival (median not reached by study end versus 12.6 months, 95% confidence interval 10.6 to 14.6 months; hazard ratio = 0.38, 95% confidence interval 0.27 to 0.53, $P < .0001$). Objective response rates, rates of disease progression, and adverse event rates were similar between groups. No deaths were attributed directly to either intervention. Ablation-related complications were reported in 76% of participants. Of those, 30 cases (20%) involved major complications, including pneumothorax (10%), pleural effusion (7%), and pulmonary infection (7%). All of the patients with these complications recovered with treatment. Minor complications occurred in 56 (38%) cases (Wei, 2020).

A systematic review and meta-analysis of eight studies compared the survival outcomes of participants with stage 1 disease who underwent either surgical resection (n = 460) or radiofrequency or microwave ablation (total n = 332). There was no significant difference in overall survival between lobectomy and microwave ablation, whereas one- and two-year overall survival rates were higher with sublobar resection (wedge resection or segmentectomy) versus radiofrequency ablation (reported as odds ratio [95% confidence interval]: 2.85 [1.33 to 6.10] versus 4.54

[2.51 to 8.21]) (Chan, 2021).

A systematic review of 12 retrospective studies (n = 985 participants with 1,336 lung nodules of various stages) found estimates of local recurrence ranged from 9% to 37%. Studies published after 2011 and those with tumors smaller than 3 to 4 centimeters reported more favorable recurrence rates. The most common complication was pneumothorax, with grade 3 or higher complications infrequently encountered (Nelson, 2019).

A systematic review and meta-analysis of seven nonrandomized comparative studies examined the overall survival of participants with various stages of disease treated with radiofrequency ablation (n = 246) and microwave ablation (n = 319). There were no significant between-group differences in overall survival rates at six months (radiofrequency ablation 89.2% versus microwave ablation 88.9%), one year (77.6% versus 79.9%), two years (59.1% versus 60.0%), and three years (36.1% versus 45.5%). There were no between-group differences in postoperative complication rates; the most common complications were pneumothorax, hemoptysis, pleural effusion, and subcutaneous emphysema (Sun, 2019).

A meta-analysis of 53 studies (n = 3,432), including 12 studies of microwave ablation, estimated that one-, two, three-, four-, and five-year overall survival rates were higher for participants treated with radiofrequency ablation compared with those treated by microwave ablation, although long-term data were limited (all $P < .05$). There were no significant between-group differences in median overall survival, median progression-free survival, median local tumor progression-free survival, complete ablation rate, or adverse event rates. In participants with pulmonary metastases, the medial overall survival was higher for those treated with radiofrequency ablation than microwave ablation (Yuan, 2019).

Kidney tumors

Renal cell carcinoma is the most common type of kidney cancer, and most patients present with localized, potentially curative disease. For small, clinically localized disease (stage T1a), partial nephrectomy is the standard of care. For most larger stage T1b tumors confined to the kidney, partial or radical nephrectomy is preferred. However, for patients who cannot tolerate or do not wish to proceed with conventional surgery or active surveillance, percutaneous image-guided thermal ablation may be a valid, curative, and tissue-sparing option.

However, there is insufficient evidence to support the safety and efficacy of microwave ablation for treating kidney tumors. The highest quality evidence from population-based registry studies and systematic reviews supports radiofrequency ablation and cryoablation. The evidence for microwave ablation is far more limited, and no randomized controlled trials of microwave ablation have been published as of this writing. Compared with partial nephrectomy, image-guided thermal ablation is associated with lower overall survival and local control, but greater preservation of renal function and lower complication rates. There is insufficient evidence to support one ablative method over another or to assess long-term outcomes.

The National Comprehensive Cancer Network (2023a) states thermal ablation (e.g., cryosurgery or radiofrequency ablation) is a treatment option for patients with clinical stage T1 renal lesions. For masses larger than 3 centimeters, thermal ablation may be an option in select patients, although it cautions ablation is associated with higher rates of local recurrence/persistence and complications with larger masses. Ablative methods may require multiple treatments to achieve the same local oncologic outcomes as conventional surgery. Microwave ablation was not mentioned specifically.

The American Urological Association recommends thermal ablation as an alternative to surgery for treatment of clinical T1a solid renal masses smaller than 3 centimeters in size. For patients who elect thermal ablation, the percutaneous technique is preferred over a surgical approach, whenever feasible, to minimize morbidity (Moderate Recommendation; Evidence Level: Grade C). Either radiofrequency ablation or cryoablation may be

offered for thermal ablation (Conditional Recommendation; Evidence Level: Grade C). Microwave ablation was not mentioned specifically (Campbell, 2021).

The Society of Interventional Radiology issued the following recommendations (Morris, 2020):

- Percutaneous thermal ablation is a safe and effective treatment for patients with either small renal tumors (stage T1a, generally 4 centimeters or smaller) or suspected T1a renal cell carcinoma (Level of Evidence: C; Strength of Recommendation: Moderate).
- Percutaneous thermal ablation may be appropriate for high-risk patients with T1b renal cell carcinoma (between 4 and 7 centimeters) who are not surgical candidates (Level of Evidence D; Strength of Recommendation: Weak).
- Percutaneous thermal ablation of oligometastatic disease may be appropriate in patients with surgically resectable primary renal cell carcinoma who are not candidates for metastasectomy (Level of Evidence D; Strength of Recommendation: Weak).
- Radiofrequency ablation, cryoablation, and microwave ablation are all appropriate modalities for thermal ablation, and method of ablation should be left to the discretion of the operating physician (Level of Evidence: D; Strength of Recommendation: Weak).

The Society of Interventional Radiology issued quality improvement standards for percutaneous ablation in renal cell carcinoma. According to these standards, most patients undergoing the procedure should have T1a disease for whom major post-procedural complications have been reported in up to 6% of patients, with an overall complication rate of up to 21%. The most common complications include hemorrhage, abscess, or unintentional damage to adjacent structures. Contraindications to image-guided thermal ablation include an uncorrectable coagulopathy, active urinary tract infection, lack of safe percutaneous access to the tumor, and the inability to create an appropriate ablation zone without damaging nearby critical structures such as bowel or the ureter (Gunn, 2020).

A systematic review and network meta-analysis examined oncologic outcomes of image-guided thermal ablation procedures in participants with T1b renal clear cell carcinoma. Nine trials were included, but only two (n = 63) reported outcomes specifically for microwave ablation. All studies found thermal ablation methods to be safe with low recurrence rates and low occurrence of high-grade complications. The authors found no statistical differences between microwave ablation and partial or radical nephrectomy. Due to the small number and heterogeneity of studies, more trials are necessary to determine procedural benefit (Cazalas, 2021).

A systematic review and network meta-analysis of 47 low-to-moderate quality studies compared the outcomes of different nephron-sparing techniques for treatment of small renal masses: partial nephrectomy (n = 15,238), radiofrequency ablation (n = 1,877), cryoablation (n = 6,618), and microwave ablation (n = 344, five studies). The mean tumor size for microwave ablation was 2.74 centimeters; mean tumor sizes were comparable across all groups. Participants receiving thermal ablation were older and had more comorbidities than those receiving partial nephrectomy. Partial nephrectomy exhibited higher overall survival and local control than thermal ablative therapies, but not necessarily better cancer-specific mortality ($P < 0.001$). Limited evidence suggests ablative techniques may have a superior complication profile and renal function preservation compared to partial nephrectomy, but the superiority of any one ablative method has not been established (Uhlig, 2019).

References

On May 24, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers

for Medicare & Medicaid Services. Search terms were “microwave ablation,” “lung neoplasm” (MeSH), “lung cancer,” and “renal cell carcinoma.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

7/2023: initial review date and clinical policy effective date: 7/2023

Opioid Treatment

Plan: AmeriHealth Caritas Louisiana

Clinical Policy ID: CCP.4039

Recent review date: 11/2023

Next review date: 3/2025

Policy contains: Opioid treatment; medication-assisted treatment; opioid use disorder; substance use disorder.

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Policy statement

AmeriHealth Caritas Louisiana provides coverage for medically necessary Medication-Assisted Treatment (MAT) delivered in Opioid Treatment Programs (OTPs), including but not limited to Methadone treatment to all AmeriHealth Caritas Louisiana-eligible adults and adolescents with Opioid Use Disorder (OUD).

Components

Screening

A screening is conducted to determine eligibility and appropriateness for admission and referral.

Physician Examination

A complete physical examination, including a drug screening test, by the OTP's physician must be conducted before admission to the OTP. A full medical exam, including results of serology and other tests, must be completed within 14 days of admission. The physician shall ensure members have a Substance Use or Opioid Use Disorder. The member must have been addicted to opiates for at least one year before admission for treatment, or meet exception criteria, as set in federal regulations, as determined by a physician.

Alcohol and Drug Assessment and Referrals

A comprehensive bio-psychosocial assessment must be completed within the first seven (7) days of admission, which substantiates treatment. For new admissions, the American Society of Addiction Medicine (ASAM) 6 Dimensional risk evaluation must be included in the assessment. The assessment must be reviewed and signed by a licensed mental health professional (LMHP). The comprehensive bio-psychosocial assessment shall contain the following:

- Circumstances leading to admission;
- Past and present behavioral health concerns;
- Past and present psychiatric and addictive disorders treatment;
- Significant medical history and current health status;
- Family and social history;
- Current living situation;
- Relationships with family of origin, nuclear;
- Family and significant others;
- Education and vocational training;
- Employment history and current status;
- Military service history and current status;
- Legal history and current legal status;
- Emotional state and behavioral functioning, past and present; and
- Strengths, weaknesses, and needs.

Ongoing assessment and referral services for individuals presenting a current or past use pattern of alcohol or other drug use is essential in the treatment of substance use disorders. The assessment is designed to gather and analyze information regarding a member's biopsychosocial, substance use and treatment history. The purpose of the assessment is to provide sufficient information for problem identification and, if appropriate, substance use-related treatment or referral. A licensed provider shall comply with licensing standards and any further LDH standards outlined below in regard to assessment practices. Once an individual receives an assessment, a staff member shall provide the individual with the identified clinical recommendations, including referral to alternative level of care or services. Assessments shall include the consideration of appropriate psychopharmacotherapy. There shall be evidence that the member was assessed to determine if MAT was a viable option of care, based on the Substance Use Disorder (SUD) diagnosis, and an appropriate assignment to level of care was determined, with referral to other appropriate services as indicated.

OTP providers, when clinically appropriate, shall address the following during the assessment and referral process:

- Educate members on the proven effectiveness, benefits and risks of Food and Drug Administration approved MAT options for their SUD;
- Refer to other MAT offsite as applicable; and
- Document member education, access to MAT and member response in the progress notes.

Treatment Planning Process

Treatment plans shall be based on the assessments to include person-centered goals and objectives. The treatment plan shall be developed within 7 days of admission by the treatment team. The treatment plan shall:

- Identify the services intended to reduce the identified condition, as well as the anticipated outcomes of the individual;
- Include a referral to self-help groups such as Alcoholics Anonymous (AA), Al-Anon, and Narcotics Anonymous (NA);
- Must specify the frequency, amount and duration of services;
- Must be signed by the LMHP or physician responsible for developing the plan; and
- Specify a timeline for re-evaluation of the plan that is, at least, an annual redetermination.

The re-evaluation shall involve the individual, family and providers and shall determine whether services have contributed to meeting the stated goals. The treatment plan shall be updated and revised if there is no measureable reduction of disability or restoration of functional level. The updated plan shall identify different rehabilitation strategies with revised goals and services. If the services are being provided to a youth enrolled in the Coordinated System of Care (CSoC) program, the wrap-around agency (WAA) must be notified, and the substance use treatment provider must either be on the Child Family Team (CFT) or will work closely with the CFT. Substance use service provision will be part of the youth's plan of care (POC) developed by the team.

Treatment Services

Treatment services include:

- The administration and dispensing of medications;
- Treatment phases 1 through 4;
    - Initial treatment phase lasts from three to seven days. During this phase, the provider conducts orientation, provides individual counseling and develops the initial treatment plan for treatment of critical health or social issues.
    - Early stabilization begins on the third to seventh day following initial treatment through 90 days in duration, whereas the provider:
        - Conducts weekly monitoring of the member's response to medication;
        - Provides at least four individual counseling sessions;
        - Revises the treatment plan within 30 days to include input by all disciplines, the member and significant others; and
        - Conducts random monthly drug screen tests.
- Maintenance treatment follows the end of early stabilization and lasts for an indefinite period of time. The provider shall:
    - Perform random monthly drug screen tests until the member has negative drug screen tests for 90 consecutive days as well as random testing for alcohol when indicated;
    - Thereafter, monthly testing to members who are allowed six days of take-home doses, as well as random testing for alcohol when indicated;
    - Continuous evaluation by the nurse of the member's use of medication and treatment from the program and from other sources;
    - Documented reviews of the treatment plan every 90 days in the first two years of treatment by the treatment team;
    - Documentation of response to treatment in a progress note at least every 30 days;
    - Medically supervised withdrawal from synthetic narcotic with continuing care (only when withdrawal is requested by the member). The provider shall:

        - Decrease the dose of the synthetic narcotic to accomplish gradual, but complete withdrawal, as medically tolerated by member;
        - Provide counseling of the type and quantity based on medical necessity; and
        - Conduct discharge planning as appropriate.
- Take Home Dosing
    - Participants may receive take home doses in accordance with state and federal regulations and the member's treatment plan phase. Take Home Dosing is a privilege contingent upon the member's progress in treatment and surroundings absent of criminal activity and based upon the probability of the member's risk of diversion which is determined by assessment and clinical judgement; and
    - Guidelines for Take Home Medication Privilege:
        - Negative drug/alcohol screen for at least 30 days;
        - Regular clinic attendance;
        - Absence of serious behavioral problems and criminal activity during treatment;
        - Stability of home environment and social relationships; and
        - Assurance that take-home medication can be safely stored (lock boxes provided by member).
- Standard Schedule:
    - After the first 30 days and during the remainder of the first 90 days in treatment, one therapeutic privilege dose per week may be allowed (days 30-90);
    - In the second 90 days, two therapeutic doses per week may be allowed (days 91-180);
    - In the third 90 days of treatment, three therapeutic doses per week may be allowed;
    - In the final 90 days of treatment of the first year, four therapeutic doses per week may be allowed;
    - After one year in treatment, a six-day dose supply, consisting of take home doses and therapeutic doses may be allowed once a week if the treatment team and medical director determine that the therapeutic privilege doses are appropriate; and
    - After two years in treatment, a 13-day dose supply, consisting of take home doses and therapeutic doses may be allowed once every two weeks if the treatment team and medical director determine that the therapeutic privilege doses are appropriate.
- Exceptions:
    - When the OTP is closed for a legal holiday or Sunday, a take home dose may be dispensed to members who have attended the clinic at least two times and who have been determined by the nurse to be physically stable and by the counselor to create a minimal risk for diversion; and
    - In the event of a Governor's Declaration of Emergency, emergency provisions for take home dosing may be enacted, as approved by the State Opioid Treatment Authority (SOTA).
- Loss of Take Home Privilege:
    - Positive drug screens at any time for any drug other than prescribed will require a new determination to be made by the treatment team regarding take home privileges; and
    - If the member has a urine drug screen with any substances other than Methadone, Methadone Metabolites, or a medication that the member does not have a valid prescription for, then take home doses may be eliminated and the member would then present to the provider's office in person.

- Care coordination:
    - Services provided to members must include communication and coordination with the other health providers as it relates to the member's OUD treatment. Coordination with other health care systems shall occur, as needed, to achieve the treatment goals. All coordination must be documented in the member's treatment record.

Eligibility Criteria

The medical necessity for substance use services must be determined by and recommended by a physician. Members who meet clinical criteria must be at least 18 years old, unless the member has consent from a parent or legal guardian, if applicable, and the State Opioid Treatment Authority. Members must also meet member admission criteria for federal opioid treatment standards in accordance with **42** CFR §8.12, as determined by a physician.

Member Records

In addition to the general requirements for Record Keeping (refer to Section 2.6), each member's record shall contain **the following**:

- Recording of medication administration and dispensing in accordance with federal and state requirements;
- Results of five most recent drug screen tests with action taken for positive results;
- Physical status and use of additional prescription medication;
- Contact notes and progress notes (monthly, or more frequently, as indicated by needs of client) which include employment/vocational needs, legal and social status, and overall individual stability;
- Documentation and confirmation of the factors to be considered in determining whether a take-home dose is appropriate;
- Documentation of approval of any exception to the standard schedule of take-home doses and the physician's justification for such exception; and
- Any other pertinent information.

Additional Provider Responsibilities

OTPs must maintain an up-to-date disaster and emergency plan, which has been approved by the SOTA. In the event of an emergency leading to temporary closure of a program, an up-to-date plan for emergency administration of medications must be addressed. OTPs should have the capability to respond to emergencies on a 24-hour basis. The plan should include a contracted physician with whom the provider can contact during emergencies. The plan should also include a mechanism for informing members of emergency arrangements and alternative dosing locations and a procedure for notifying SAMHSA, DEA, and state authorities of the event.

OTPs must coordinate access to the Methadone Central Registry for employees who provide direct member care. Access should be coordinated through an email request to the State Opioid Treatment Authority. The OTP should assign access to more than one person to update the Methadone Central Registry. Updates should occur on a daily basis and/or as changes in prescribed doses occur.
Monthly census and capacity reports must be submitted to the SOTA by the fifth of each month using appropriate documentation format as approved by the SOTA.

Upon the death of a member, the OTP shall:

- Report the death of a member enrolled in their clinic to the SOTA within 24 hours of the discovery of the member's death;
- Report the death of a member to the Health Standards Section (HSS) within 24 hours of discovery if the death is related to program activity;
- Submit documentation on the cause and/or circumstances to SOTA and to HSS, if applicable, within 24 hours of the provider's receipt of the documentation; and
- Adhere to all protocols established by LDH on the death of a member.

Guest dosing occurs when a member receives Methadone dosing at another OTP other than their primary/home based OTP clinic. Guest dosing can be coordinated with the State Opioid
Treatment Authority during natural disasters if the prescriber is unable to contact the provider with whom the member is affiliated. The providers involved in a temporary transfer or guest dosing shall ensure the following:

- The receiving provider shall verify dosage prior to dispensing and administering medication;
- The sending provider shall verify dosage and obtain approval and acceptance from receiving provider prior to member's transfer; and
- Documentation to support all temporary transfers and guest dosing is maintained.

Non-preferred forms of buprenorphine and buprenorphine/naloxone require prior authorization.

Services provided to adolescents must include communication and coordination with the family and/or legal guardian. Coordination with other child-serving systems should occur, as needed, to achieve the treatment goals. All coordination must be documented in the youth's medical record. All substance use treatment services shall offer the family component. Adolescent substance use programs shall include family involvement, parent education and family therapy.

Staffing for the facility must be consistent with State licensure regulations on a full-time employee (FTE) basis.

Provider Qualifications

Agency

To provide services, OTPs must meet the following requirements:

- Licensed by the Louisiana Department of Health (LDH) per La. R.S. 40:2151 et seq.;
- OTPs must be accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Accreditation (COA), or The Joint Commission (TJC). Denial, loss of, or any negative change in accreditation status must be reported in writing immediately upon notification to AmeriHealth Caritas Louisiana, with whom the agency contracts or is being reimbursed;
- Services must be provided under the supervision of a licensed mental health professional (LMHP) or physician who is acting within the scope of his/her professional license and applicable state law. (Refer to Appendices B and D for more information on LMHPs.) The term supervision refers to clinical support, guidance and consultation afforded to unlicensed staff, and should not be confused with clinical supervision of bachelor's or master's level individuals or provisionally licensed individuals pursuing licensure. Such individuals must comply with current, applicable scope of practice and supervisory requirements identified by their respective licensing boards;

- Arrange for and maintain documentation that prior to employment (or contracting, volunteering, or as required by law) individuals pass criminal background checks, including sexual offender registry checks, in accordance with all of the below:
    - The Behavioral Health Service Provider (BHSP) licensing regulations established by the Louisiana Administrative Code (LAC) 48:I.Chapter 56, which includes those for owners, managers, and administrators; any individual treating children and/or adolescents; and any unlicensed direct care staff;
    - La. R.S. 40:1203.1 et seq. associated with criminal background checks of un-licensed workers providing member care;
    - La. R.S. 15:587, as applicable; and
    - Any other applicable state or federal law.
- Providers shall not hire individuals failing to meet criminal background check requirements and regulations. Individuals not in compliance with criminal background check requirements and regulations shall not be utilized on an employment, contract nor volunteer basis. Criminal background checks performed over 90 days prior to the date of employment will not be accepted as meeting the criminal background check requirement. Results of criminal background checks are to be maintained in the individual's personnel record;
- The provider must review the Department of Health and Human Services' Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and the LDH State Adverse Actions website prior to hiring or contracting with any employee or contractor that performs services that are compensated with AmeriHealth Caritas Louisiana funds, including but not limited to licensed and unlicensed staff, interns and contractors. Once employed, the lists must be checked once a month thereafter to determine if there is a finding that an employee or contractor has abused, neglected or extorted any individual or if they have been excluded from participation in AmeriHealth Caritas Louisiana or the Department of Health and Human Services' Office of Inspector General. The provider is prohibited from knowingly employing or contracting with, or retaining the employment of or contract with, anyone who has a negative finding placed on the Louisiana State Adverse Action List, or who have been excluded from participation in AmeriHealth Caritas Louisiana or the Department of Health and Human Services' Office of Inspector General;
- Providers are required to maintain results in personnel records that checks have been completed. The OIG maintains the LEIE on the OIG website (https://exclusions.oig.hhs.gov) and the LDH Adverse Action website is located at https://adverseactions.ldh.la.gov/SelSearch;
- Arrange for and maintain documentation that all persons, prior to employment, are free from Tuberculosis (TB) in a communicable state via skin testing (or chest exam if recommended by physician) to reduce the risk of such infections in members and staff. Results from testing performed over 30 days prior to date of employment will not be accepted as meeting this requirement;
- Establish and maintain written policies and procedures inclusive of drug testing staff to ensure an alcohol and drug-free workplace and a workforce free of substance use;
- Maintain documentation that all direct care staff, who are required to complete First Aid, cardiopulmonary resuscitation (CPR) and seizure assessment training, complete American Heart Association (AHA) recognized training within 90 days of hire, which must be renewed within a time period recommended by the AHA;

- Maintain documentation of verification of staff meeting educational and professional requirements, licensure (where applicable), as well as completion of required trainings for all staff. Quarterly trainings must be documented and submitted to the SOTA on a quarterly basis; and
- Ensure and maintain documentation that all unlicensed persons employed by the organization complete training in a recognized crisis intervention (CI) curriculum prior to handling or managing crisis calls, which must be updated annually.

Staff

To provide services, staff must meet the following requirements:

- Licensed and unlicensed professional staff must be at least 18 years of age, with a high school diploma or equivalent according to their areas of competence as determined by degree, required levels of experience as defined by State law and regulations and departmentally approved guidelines and certifications;
- Effective six (6) months after publication date, staff must be at least three years older than any member served under 18 years of age. Licensed individual practitioners with no documentation of having provided substance use services prior to December 1, 2015, are required to demonstrate competency via the

  Alcohol and Drug Counselor (ADC) exam, the Advanced Alcohol and Drug Counselor (AADC) exam, or the Examination for Master Addictions Counselor (EMAC). Any licensed individual practitioner, who has documentation of providing substance use services prior to December 1, 2015, and within their scope of practice is exempt from (ADC, AADC, EMAC) testing requirements. Organizational agencies are required to obtain verification of competency (passing of accepted examinations) or exemption (prior work history/resume, employer letter);
- Staff can include the Office of Behavioral Health (OBH) credentialed peer support specialists who meet all other qualifications. A peer specialist is a recommended position at all ASAM levels of care. A peer specialist is a person with lived experience with behavioral health challenges, who is in active recovery and is trained to assist others in their own recovery. The peer specialist uses their own unique, life-altering experience in order to guide and support others who are in recovery. This refers to individuals recovering from substance use disorders. Peer specialist work in conjunction with highly trained and educated professionals. They fill a gap by providing support from the perspective of someone who has first-hand experience;
- The provider is prohibited from knowingly employing or contracting with, or retaining the employment of or contract with, a member of the direct care staff who has an alcohol or drug offense, unless the employee or contractor has completed his/her court-ordered sentence, including community service, probation and/or parole and been sober per personal attestation for at least the last two years;
- Satisfactory completion of criminal background checks pursuant to the BHSP licensing regulations (LAC 48:I.Chapter 56), La R.S. 40:1203.1 et seq., La R.S. 15:587 (as applicable), and any applicable state or federal law or regulation;
- Pass a TB test prior to employment;
- Pass drug screening tests as required by agency's policies and procedures;
- Employees and contractors must not be excluded from participation in the Medicaid or Medicare Program by Louisiana Medicaid or the Department of Health and Human Services' Office of Inspector General;
- Direct care staff must not have a finding on the Louisiana State Adverse Action List;

- Complete AHA recognized First Aid, CPR and seizure assessment training. Psychiatrists, advanced practical registered nurses (APRNs)/clinical nurse specialists (CNSs)/physician assistants (PAs), registered nurses (RNs) and licensed practical nurses (LPNs) are exempt from this training;
- All direct care staff shall receive orientation and training for and demonstrate knowledge of the following, including, but not limited to:
    - symptoms of opiate withdrawal;
    - drug screen testing and collections;
    - current standards of practice regarding opiate addiction treatment;
    - poly-drug addiction; and
    - information necessary to ensure care is provided within accepted standards of practice; and
- Non-licensed direct care staff are required to complete a basic clinical competency training program approved by OBH prior to providing the service.

Staffing Requirements

Personnel must consist of professional and other support staff that are adequate to meet the needs of the individuals admitted to the facility.

The OTP shall have the following staff:

Medical Director

The provider shall ensure that its medical director is a licensed physician with a current, valid unrestricted license to practice in the state of Louisiana with two years of qualifying experience in treating psychiatric disorders.

The medical director shall provide the following services:

- Decrease the dose to accomplish gradual, but complete withdrawal, only when requested by the member;
- Provide medically approved and medically supervised assistance for withdrawal, only when requested by the member;
- Participate in the documentation of reviews of treatment plan every 90 days in the first two years of treatment;
- Order take home doses; and
- Participate in discharge planning.

Pharmacist or Dispensing Physician

The OTP shall employ or contract with a pharmacist or dispensing physician to assure that any prescription medication dispensed on-site meets the requirements of applicable state statutes and regulations. The pharmacist or dispensing physician shall have a current, valid unrestricted license to practice in the state of Louisiana and provide the following services:

- Dispense all medications;
- Work collaboratively with the Medical Director to decrease the dose to accomplish gradual, but complete withdrawal, only when requested by the member;
- Contribute to the development of the initial treatment plan;

- Contribute to the documentation for the treatment plan review every 90 days in the first two years of treatment; and
- Document response to treatment in progress notes at least every 30 days.

Clinical Supervisor

State regulations require supervision of unlicensed professionals by a clinical supervisor, who:

- Is an LMHP that maintains a current and unrestricted license with its respective professional board or licensing authority in the state of Louisiana;
- Shall be on duty and on call as needed;
- Has two years of qualifying clinical experience as an LMHP in the provision of services provided by the provider;
- Shall have the following responsibilities:
    - Provide supervision utilizing evidenced-based techniques related to the practice of behavioral health counseling;
    - Serve as resource person for other professionals counseling persons with behavioral health disorders;
    - Attend and participate in care conferences, treatment planning activities, and discharge planning;
    - Provide oversight and supervision of such activities as recreation, art/music or vocational education;
    - Function as member advocate in treatment decisions;
    - Ensure the provider adheres to rules and regulations regarding all behavioral health treatment, such as group size, caseload, and referrals;
    - Provide only those services that are within the person's scope of practice; and
    - Assist the clinical director and/or medical director and governing body with the development and implementation of policies and procedures.

Physician or APRN

The physician or APRN shall have a current, valid unrestricted license to practice in the state of Louisiana. The physician or APRN shall be on-site as needed or on-call as needed during the hours of operations to provide the following services:

- Examine member for admission (physician only)
- Administer medications;
- Monitor the member's response to medications;
- Evaluate of member's use of medication and treatment from the program and other sources;
- Contribute to the development of the initial treatment plan;
- Contribute to the documentation regarding the response to treatment for treatment plan reviews;
- Contribute to the documentation for the treatment plan review every 90 days in the first two years of treatment;
- Conduct drug screens; and
- Participate in discharge planning.

Nursing Staff

Nursing staff shall have a current, valid and unrestricted nursing license in the State of Louisiana and provide the following services:

- Administer medications;
- Monitor the member's response to medications;
- Evaluate of member's use of medication and treatment from the program and other sources;
- Document response to treatment in progress notes at least every 30 days;
- Contribute to documentation for the treatment plan review every 90 days in the first two years of treatment;
- Conduct drug screens; and
- Participate in discharge planning.

Licensed Mental Health Professional (LMHP)

Licensed Mental Health Professionals (LMHPs) shall have a current, valid and unrestricted license in the State of Louisiana, and must comply with current, applicable scope of practice and supervisory requirements identified by their respective licensing boards. The LMHP providing substance use treatment services shall have documented credentials, experience and/or training in working with members who have substance use disorders, which shall be maintained in the individual's personnel record.

Licensed Mental Health Professionals provide the following services:

- Conduct orientation;
- Develop the initial plan for treatment;
- Revise treatment to include input by all disciplines, members and significant others;
- Provide individual counseling;
- Contribute to the development as well as document the initial treatment plan;
- Document response to treatment in progress notes at least every 30 days;
- Contribute to the development as well as document reviews of treatment plan every 90 days in the first two years of treatment by the treatment team; and
- Conduct in discharge planning as appropriate.

Unlicensed professionals (UPs)

UPs of substance use services must be registered with the Addictive Disorders Regulatory Authority (ADRA) and meet regulations and requirements in accordance with La. RS 37:3387 et seq. Written verification of ADRA registration and documentation of supervision when applicable shall be maintained in the individual's personnel record. Unlicensed staff who fall under a professional scope of behavioral health practice with formal board approved clinical supervision and whose scope includes the provision of substance use services will not need to register with ADRA. Unlicensed substance use providers must meet at least one of the following qualifications:

- Be a master's-prepared behavioral health professional that has not obtained full licensure privileges and is participating in ongoing professional supervision. When working in substance use treatment settings, the master's-prepared UP must be supervised by an LMHP, who meets the requirements of this Section;

- Be a registered addiction counselor;
- Be a certified addiction counselor; or
- Be a counselor-in-training (CIT) that is registered with ADRA and is currently participating in a supervision required by the Addictive Disorders practice act.

Unlicensed professionals perform the following services under the supervision of a physician or LMHP:

- Participate in conducting orientation,
- Participate in discharge planning as appropriate; and
- Provide support to the treatment team where applicable, while only providing assistance allowable under the auspices of and pursuant to the scope of the individual's license.

Staff Ratios

OTPs must maintain a sufficient level of staffing to meet the needs of the members. The caseload of each LMHP or UP shall not exceed 75 active members.

Allowed Provider Types and Specialties

- PT 68 Substance Use and Alcohol Use Center PS 70 Clinic/Group with Subspecialty 8V Methadone Clinic.

Allowed Modes of Delivery

- Individual;
- Group;
- On-site; and
- Tele-video (LMHPs only).

Telehealth

LMHP's providing assessments, evaluations, individual psychotherapy, family psychotherapy, and medication management services offered within Opioid treatment programs may be reimbursed when conducted via telecommunication technology. The LMHP is responsible for acting within the telehealth scope of practice as decided by the respective licensing board. The provider must bill the procedure code (CPT codes) with modifier "95", as well as the correct place of service, either POS 02 (other than home) or 10 (home). Reimbursement will be at the same rate as a face-to-face services.

Exclusions: Methadone admission visits conducted by the admitting physician within OTPs are not allowed via telecommunication technology.

Reimbursement

Reimbursement for Methadone for OUD treatment will only be made to OTPs, which are federally approved by SAMHSA and the DEA, and regulated by LDH, which includes OBH and HSS. A provider subspecialty code 8V has been established for the OTPs/Methadone clinics as sole source providers.

The 8V subspecialty has two bundled rate options. H0020 will be used for a bundled rate reimbursement for

Methadone treatment. H0047 will be used for a bundled rate for Buprenorphine treatment, but excludes the ingredient cost of the medication. Buprenorphine medication will be billed separately using the applicable J-codes (J0571-J0575) depending on dosage amounts.

Bundled rates for the OTPs will facilitate the practical needs of member-centered treatment in the administration of Medication Assisted Treatment (MAT) to integrate the provision of counseling and medical services. It strengthens recovery and decreases recidivism in members diagnosed within the substance use disorder spectrum.

The **section** below provides an explanation of available codes for the OTPs/Methadone clinics.

H0020 Methadone Bundled Rate
Bundled rate includes all state and federal regulatory mandated components of treatment. Services include but are not limited to the following:

- Medication: This includes the administration, dosing, and dispensing of Methadone as per the member's treatment plan;
- Counseling: Members are required to participate in group or individual sessions as part of the member's treatment plan;
- Urine Drug Testing: This includes the urine drug testing or other laboratory tests deemed medically necessary;
- Physical examinations by a physician or advanced practice registered nurse; • Evaluation and management visits;
- Evaluation and management visits;
- Case management; and
- Laboratory Services.

The OTP may be reimbursed for the bundled rate for participants receiving take home doses in accordance with state and federal regulations and the member's treatment plan phase.

Guest dosing occurs when a member receives Methadone dosing at another OTP other than their primary/home-based OTP clinic. The guest dosing provider will bill for the bundled rate and provide clinical care, if appropriate, that is coordinated with the "home" provider and Methadone Central Registry (MCR) to ensure correct dosing.

H0047 Buprenorphine Bundled Rate
Bundled rate includes all components of treatment, except for the Buprenorphine medication. Services include but are not limited to the following:

- Assessment and individualized treatment plan;
- Individual and group counseling;
- Urine Drug Testing or laboratory testing; and
- Coordination of medically necessary services.

Buprenorphine medication will be billed separately using the applicable J-codes (J0571-J0575) depending on dosage amounts.

References

Louisiana Department of Health. 2017. Behavioral Health Services Provider Manual. Opioid Treatment. Chapter 2, Section 2.4. Issued March 6, 2023. https://www.lamedicaid.com/provweb1/providermanuals/manuals/bhs/bhs.pdf.

Policy updates

Initial review date: 3/1/2021

11/2023: policy references updated.

AmeriHealth Caritas Louisiana

Prostatic urethral lift/UroLift for benign prostatic hypertrophy

Clinical Policy ID: CCP.1529

Recent review date: 7/2023

Next review date: 11/2024

Policy contains: benign prostatic hyperplasia; benign prostatic hypertrophy; prostatic urethral lift; UrdLift.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage Policy

Prostatic urethral lift (UroLift) is clinically proven and, therefore, may be medically necessary for treatment of lower urinary tract symptoms due to benign prostatic hypertrophy/hyperplasia when all of the following criteria are met:

- Members age 50 and older
- Members with prostate volume between 30 and 80 milliliters
- Members with an absence of the median lobe of the prostate
- Members who have failed treatment with medications (Cornu, 2023b; Lerner, 2021a; Lerner, 2021b; National Institute for Health and Care Excellence, 2021)

Limitations

Prostatic urethral lift (UroLift) is not clinically proven, and therefore investigational, for any of the following:

- Prostate volume of >100 milliliters
- A urinary tract infection

- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence
- Current gross hematuria
- A known allergy to nickel (U.S. Food and Drug Administration, 2013)

Alternative covered services

- Medications, including alpha blockers, 5-alpha reductase inhibitors, or a combination
- Transurethral resection of the prostate
- Minimally invasive surgery, including:
- Convective radiofrequency water vapor thermal therapy
- Prostatic arterial embolization
- Temporary implantable nitinol device
- Transurethral microwave thermotherapy

Background

Benign prostatic hypertrophy, also known as hyperplasia, is relatively common in older people with a prostate. The condition is marked by symptoms of the lower urinary tract. Some cases will not require treatment, but can be addressed by watchful waiting to ensure worsening of symptoms is limited. Other cases can be treated conservatively with alpha blockers, 5-alpha reductase inhibitors, or a combination. However, these medications are not always effective, and are associated with elevated risk of ejaculatory and erectile dysfunction (Garcia, 2015).

For cases requiring surgery, transurethral resection of the prostate has long been the preferred approach. Over time, efforts to develop less invasive procedures — which offer shorter operating room time, faster recovery, and fewer side effects — have been made. Transurethral needle ablation of the prostate and transurethral microwave thermotherapy are two such procedures, but both have been used less frequently over time.

Among the more recent less invasive procedures is prostatic urethral lift, which retracts obstructing prostatic lobes. The procedure begins with a cystoscopy to inspect the bladder neck and prostate, especially the middle and lateral lobes. A disposable cartridge delivers an implant consisting of a capsular nitinol tab and a urethral stainless steel tab held together by a non-absorbable suture, which draws the prostatic urethra to the capsule. The procedure creates a channel from the bladder neck to the verumontanum (Garcia, 2015).

One end of an implant is attached to the surface of the prostatic capsule, and the other end is inside the urethra. The procedure typically uses about four implants to widen the urethra. The procedure is performed under local or general anesthesia, usually in an outpatient setting (National Institute for Health and Care Excellence, 2021).

In 2013, the U.S. Food and Drug Administration gave approval to the UroLift System UL400 (NeoTract Inc., Pleasonton, CA) for the use of UroLift for benign prostatic hyperplasia in patients older than 45 years (U.S. Food and Drug Administration, 2013). In 2017, approval was expanded to include the UL500 model for lateral and median lobe prostate hyperplasia (U.S. Food and Drug Administration, 2017).

The American Board of Urology reports that prostatic urethral lift increased significantly since its introduction in 2015, and currently accounts for one-third of all procedures for benign prostatic hyperplasia (Zhang, 2023).

Findings

An American Urological Association guideline recommends prostatic urethral lift for patients with urinary tract symptoms from benign prostatic hypertrophy under certain conditions:

- Prostate volume is 30 to 80 milliliters.
- An absence of an obstructive median lobe is verified.
- The patient desires preservation of erectile and ejaculatory function (Lerner, 2021a, 2021b).

A National Institute for Health and Care Excellence guideline on UroLift is similar to that of the American Urological Association, and recommends the procedure be reserved for patients 50 years and older (National Institute for Health and Care Excellence, 2021).

A European Association of Urology guideline resembles the American Urological Association in its recommendations for urethral lift for lower urinary tract symptoms in those with a prostate volume of <70 milliliters and no middle lobe who are interested in preserving ejaculatory function (Cornu, 2023a).

A Canadian Urological Association guideline recommends prostatic urethral lift for patients with lower urinary tract symptoms interested in preserving ejaculatory function with prostate volume <80 milliliters, or for patients with a small to moderate median lobe (Elterman, 2022).

Recent systematic reviews/meta-analyses produced the following findings on the effectiveness (outcomes) of prostatic urethral lift/UroLift:

- (63 studies) After prostatic urethral lift, symptoms improved from a risk-benefit perspective, but overall outcomes were not as effective as transurethral resection of the prostate (Cornu, 2023b).

- (36 studies, n = 6,380) After five years, the effectiveness of surgical/minimally invasive retreatment was 13% for UroLift versus 4% for water vapor thermal therapy (Baboudjian, 2023).

- (8 studies, n = 675) Prostatic urethral lift, compared with transurethral resection, had a significantly higher rate of re-interventions, but a significantly lower rate of major adverse events (Lucas-Cava, 2023).

- (48 studies, n = 5,035) After prostatic urethral lift, no significant changes occurred in ejaculatory/erectile function, and minimally invasive surgery could be linked with lower risk of retrograde ejaculation (Manfredi, 2022).

- (27 studies, n = 3,017, Cochrane) Prostatic urethral lift had little to no difference in urological symptom improvement versus transurethral resection, but was the most efficacious of five minimally invasive procedures (Franco, 2021, 2022).

- Prostatic urethral lift had similar symptom improvement/adverse event rate versus other minimally invasive procedures at three, six, and 12 months. Transurethral resection had superior outcomes in each time period (Sajan, 2022).

- (47 studies) Urethral lift had lower improvements in prostate scores than other procedures, and had the highest five-year cost (e.g., $9,580 versus $6,328 compared to transurethral resection) (Chughtai, 2022).

- (48 studies, n = 5,159) Urethral lift had the highest rate of erectile function at one, six, 12, and 24 months compared with other minimally invasive procedures (Light, 2021).

- (n = 2,942) After UroLift, the in-hospital complication rate was 3.4%, while 93% of patients were catheter-free within 30 days. Re-treatment rates at one and two years were 5.2% and 11.9% (Page, 2021).

- (11 studies, n = 1,443) Effects of prostatic urethral lift weaken over time (patients were tracked at 24 months); not as effective as transurethral resection; UroLift is safe and effective in selected patients (Jing, 2020).

- (5 studies, n = 322) After 24 months, prostatic urethral lift was well-tolerated and provided favorable outcomes in symptoms, sexual health, and outcomes (Tanneru, 2020).

References

- On May 24, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were benign prostatic hyperplasia; benign prostatic hypertrophy; prostatic urethral lift; UroLift We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Baboudjian M, Cornu J-N, Gondran-Tellier B, et al. Pharmacologic and surgical retreatment after office-based treatments for benign prostatic hyperplasia: A systematic review. *Eur Urol Focus*. 2023;S2455-4569(23)00066-4. Doi: 10.1016/j.euf.2023.03.004.

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Policy updates

7/2023: initial review date and clinical policy effective date: **7/2023**