



Louisiana

Prostatic Urethral Lift

Policy # 00480

Original Effective Date: 10/21/2015

Current Effective Date: 12/01/2020

Retired Effective Date: 03/16/2016

Returned to Active Status: 12/01/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia when all of the following criteria are met to be **eligible for coverage:****

Patient Selection Criteria

Coverage eligibility for prostatic urethral lift will be considered when all of the following criteria are met:

- The patient has persistent or progressive lower urinary tract symptoms despite medical therapy (α_1 -adrenergic antagonists maximally titrated, 5 α -reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of no less than 6 months, or is unable to tolerate medical therapy; AND,
- Prostate gland volume is ≤ 80 mL; AND,
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; AND,
- Patient does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); AND,
- Patient has had appropriate testing to exclude diagnosis of prostate cancer; AND,
- Patient does not have a known allergy to nickel, titanium or stainless steel; AND,
- The patient is 45 years of age or older.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of prostatic urethral lift in other situations, including repeat procedures, to be **investigational**.*

The use of prostatic urethral lift when patient selection criteria are not met is considered to be **investigational**.*

Background/Overview

Benign Prostatic Hyperplasia

BPH is a common disorder among older individuals that results from hyperplastic nodules in the periurethral or transitional zone of the prostate. The clinical manifestations of BPH include increased urinary frequency, nocturia, urgency or hesitancy to urinate, and a weak stream when urinating. The urinary tract symptoms often progress with worsening hypertrophy and may lead to acute urinary retention, incontinence, renal insufficiency, and/or urinary tract infection.

Two scores are widely used to evaluate BPH-related symptoms: the American Urological Association Symptom Index (AUASI) and the International Prostate Symptom Score (IPSS). The AUASI is a self-administered 7-item questionnaire assessing the severity of various urinary symptoms. Total AUASI scores range from 0 to 35, with overall severity categorized as mild (≤ 7), moderate (8-19), or severe (20-35). The IPSS incorporates questions from the AUASI and a quality of life question or a "Bother score."

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

One implantable transprostatic tissue retractor system has been cleared for marketing by the FDA through the 510(k) process. In 2013, the NeoTract UroLift[®] System UL400 (NeoTract) was cleared (after receiving clearance through the FDA's de novo classification process in March 2013;

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K130651/DEN130023). In 2016, the FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to BPH in individuals ages 50 years and older. In 2017, the FDA expanded the indication for the UL400 and UL500 to include *lateral and median* lobe hyperplasia in men 45 years or older. An additional clearance in 2019 (K193269) modified one contraindication from men with prostate volume of >80 cc to men with prostate volume of >100 cc. FDA product code: PEW.

Rationale/Source

Benign prostatic hyperplasia (BPH) is a common condition in older individuals that can lead to increased urinary frequency, an urgency to urinate, a hesitancy to urinate, nocturia, and a weak stream when urinating. The prostatic urethral lift (PUL) procedure involves the insertion of one or more permanent implants into the prostate, which retracts prostatic tissue and maintains an expanded urethral lumen.

For individuals who have lower urinary tract obstruction symptoms due to BPH who do not have sufficient response to medical therapy or are experiencing significant side effects with medical therapy and receive a PUL, the evidence includes systematic reviews, randomized controlled trials (RCTs), and noncomparative studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. One RCT, the BPH6 study, compared the PUL procedure with transurethral resection of the prostate and reported that the PUL procedure was noninferior for the study's composite endpoint, which required concurrent fulfillment of six independently validated measures of symptoms, safety, and sexual health. While transurethral resection of the prostate was superior to PUL in managing lower urinary tract symptoms, PUL did provide significant symptom improvement over two years. PUL was further superior to transurethral resection of the prostate in preserving ejaculatory function. These findings were corroborated by another RCT (the LIFT study), which compared PUL with sham control. Patients underwent washout of BPH medications before enrollment. LIFT reported that patients with the PUL procedure, compared with patients who had sham surgery and no BPH medication, had greater improvements in lower urinary tract symptoms without worsened sexual function at three months. After 3 months, patients were given the option to have PUL surgery; 80% of the patients with sham procedures chose that option. Publications from this trial reported that functional improvements were durable over 3-

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, 4-, and 5-year follow-ups in a subset of patients treated with PUL; there was a high number of exclusions and loss to follow-up in that group. The BPH6 and LIFT RCTs included men with prostate volume up to 80 cm³ and excluded men with median lobe obstruction. Selection criteria of patients for whom evidence is sufficient to support improvement are derived from clinical trial eligibility criteria, product labeling, and clinical input. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017

In response to requests, while this policy was under review in 2017, clinical input on the use of a prostatic urethral lift for 3 indications were received from 4 respondents, including 2 physician-level responses identified through a specialty society and 2 physician-level responses identified through an academic medical center. Evidence from clinical input is integrated within the Rationale section summaries and the Summary of Evidence.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) published guidance on urethral lift implants to treat lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). The guidance stated:

"Current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure."

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In 2015, the National Institute for Health and Care Excellence published guidance on the use of UroLift for treating LUTS of BPH. The guidance stated: "the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia" and "the UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in individuals with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe."

American Urological Association

The American Urological Association (2018) published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were amended in 2019 and 2020. The guidelines made the following recommendations and statements regarding prostatic urethral lift (PUL).

- PUL [prostatic urethral lift] may be offered as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe.
 - "Moderate Recommendation; Evidence Level: Grade C indicating "Benefits > Risks/Burdens (or vice versa); Net benefit (or net harm) appears moderate. Applies to most patients in most circumstances but better evidence is likely to change confidence"
- "PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of with LUTS attributed to BPH."
 - "Conditional Recommendation; Evidence Level: Grade C indicating "Risks/Burdens unclear; Alternative strategies may be equally reasonable. Better evidence likely to change confidence"
- "Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally-invasive treatments for LUTS secondary to BPH."

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Prostatic Urethral Lift”, 7.01.151, 9:2020.
2. Sarma AV, Wei JT. Clinical practice. Benign prostatic hyperplasia and lower urinary tract symptoms. *N Engl J Med*. Jul 19 2012;367(3):248-257. PMID 22808960
3. Barry MJ, Fowler FJ, Jr., O'Leary MP, et al. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J Urol*. Nov 1992;148(5):1549-1557; discussion 1564. PMID 1279218
4. O'Leary M P. Validity of the bother score in the evaluation and treatment of symptomatic benign prostatic hyperplasia. *Rev Urol*. Winter 2005;7(1):1-10. PMID 16985801
5. Djavan B, Marberger M. A meta-analysis on the efficacy and tolerability of alpha1-adrenoceptor antagonists in patients with lower urinary tract symptoms suggestive of benign prostatic obstruction. *Eur Urol*. Jun 1999;36(1):1- 13. PMID 10364649
6. Foster HE, Barry MJ, Dahm P, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline. *J Urol*. Jun 11 2018. PMID 29775639
7. Reich O, Gratzke C, Bachmann A, et al. Morbidity, mortality and early outcome of transurethral resection of the prostate: a prospective multicenter evaluation of 10,654 patients. *J Urol*. Jul 2008;180(1):246-249. PMID 18499179
8. Foster HE, Barry MJ, Dahm P, et al. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE. 2020. [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(bph\)-guideline](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline).

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9. Sundaram D, Sankaran PK, Raghunath G, et al. Correlation of Prostate Gland Size and Uroflowmetry in Patients with Lower Urinary Tract Symptoms. *J Clin Diagn Res.* May 2017;11(5):AC01-AC04. PMID 28658743
10. Rosen RC, Catania JA, Althof SE, et al. Development and validation of four-item version of Male Sexual Health Questionnaire to assess ejaculatory dysfunction. *Urology.* May 2007;69(5):805-809. PMID 17482908
11. Cappelleri JC, Rosen RC. The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *Int J Impot Res.* Jul-Aug 2005;17(4):307-319. PMID 15875061
12. Sonksen J, Barber NJ, Speakman MJ, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12-month results from the BPH6 study. *Eur Urol.* Oct 2015;68(4):643-652. PMID 25937539
13. Barry MJ, Williford WO, Chang Y, et al. Benign prostatic hyperplasia specific health status measures in clinical research: how much change in the American Urological Association symptom index and the benign prostatic hyperplasia impact index is perceptible to patients? *J Urol.* Nov 1995;154(5):1770-1774. PMID 7563343
14. Roehrborn CG, Wilson TH, Black LK. Quantifying the contribution of symptom improvement to satisfaction of men with moderate to severe benign prostatic hyperplasia: 4-year data from the CombAT trial. *J Urol.* May 2012;187(5):1732-1738. PMID 22425127
15. McVary KT, Roehrborn CG, Avins AL, et al. American Urological Association Guideline: Management of Benign Prostatic Hyperplasia (BPH). 2010 (affirmed 2014); [http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)](http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)).
16. Perera M, Roberts MJ, Doi SA, et al. Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. *Eur Urol.* Apr 2015;67(4):704-713. PMID 25466940
17. Cantwell AL, Bogache WK, Richardson SF, et al. Multicentre prospective crossover study of the 'prostatic urethral lift' for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *BJU Int.* Apr 2014; 113(4): 615-22. PMID 24765680
18. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. *J Urol.* Dec 2013; 190(6): 2161-7. PMID 23764081

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19. McVary KT, Gange SN, Shore ND, et al. Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of prostatic urethral lift. *J Sex Med.* Jan 2014; 11(1): 279-87. PMID 24119101
20. Shore N. A Review of the Prostatic Urethral Lift for Lower Urinary Tract Symptoms: Symptom Relief, Flow Improvement, and Preservation of Sexual Function in Men With Benign Prostatic Hyperplasia. *Curr Bladder Dysfunct Rep. NA* 2015; 10(2): 186-192. PMID 25984251
21. Roehrborn CG, Rukstalis DB, Barkin J, et al. Three year results of the prostatic urethral L.I.F.T. study. *Can J Urol.* Jun 2015; 22(3): 7772-82. PMID 26068624
22. Garrido Abad P, Coloma Del Peso A, Sinues Ojas B, et al. [Urolift(R), a new minimally invasive treatment for patients with low urinary tract symptoms secondary to BPH. Preliminary results]. *Arch Esp Urol.* Jul-Aug 2013; 66(6): 584-91. PMID 23985459
23. Chin PT, Bolton DM, Jack G, et al. Prostatic urethral lift: two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urology.* Jan 2012; 79(1): 5-11. PMID 22202539
24. Woo HH, Bolton DM, Laborde E, et al. Preservation of sexual function with the prostatic urethral lift: a novel treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Sex Med.* Feb 2012; 9(2): 568-75. PMID 22172161
25. McNicholas TA, Woo HH, Chin PT, et al. Minimally invasive prostatic urethral lift: surgical technique and multinational experience. *Eur Urol.* Aug 2013; 64(2): 292-9. PMID 23357348
26. Jones P, Rajkumar GN, Rai BP, et al. Medium-term Outcomes of Urolift (Minimum 12 Months Follow-up): Evidence From a Systematic Review. *Urology.* Nov 2016; 97: 20-. PMID 27208817
27. Woo HH, Chin PT, McNicholas TA, et al. Safety and feasibility of the prostatic urethral lift: a novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). *BJU Int.* Jul 2011; 108(1): 82-8. PMID 21554526
28. Bozkurt A, Karabakan M, Keskin E, et al. Prostatic Urethral Lift: A New Minimally Invasive Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urol Int.* 2016; 96(2): 202-6. PMID 26613256
29. Ray A, Morgan H, Wilkes A, et al. The Urolift System for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A NICE Medical Technology Guidance. *Appl Health Econ Health Policy.* Oct 2016; 14(5): 515-26. PMID 26832146
30. Hoffman RM, Monga M, Elliott SP, et al. Microwave thermotherapy for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* Sep 12 2012; (9): CD004135. PMID 22972068

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31. Tanneru K, Gautam S, Norez D, et al. Meta-analysis and systematic review of intermediate-term follow-up of prostatic urethral lift for benign prostatic hyperplasia. *Int Urol Nephrol*. Jun 2020; 52(6): 999-1008. PMID 32065331
32. Rukstalis D, Rashid P, Bogache WK, et al. 24-month durability after crossover to the prostatic urethral lift from randomised, blinded sham. *BJU Int*. Oct 2016; 118 Suppl 3: 14-22. PMID 27684483
33. Sievert KD, Schonhaler M, Berges R, et al. Minimally invasive prostatic urethral lift (PUL) efficacious in TURP candidates: a multicenter German evaluation after 2 years. *World J Urol*. Jul 2019; 37(7): 1353-1360. PMID 30283994
34. Jung JH, Reddy B, McCutcheon KA, et al. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Cochrane Database Syst Rev*. May 25 2019; 5: CD012832. PMID 31128077
35. Gratzke C, Barber N, Speakman MJ, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. *BJU Int*. May 2017; 119(5): 767-775. PMID 27862831
36. Miller LE, Chughtai B, Dornbier RA, et al. Surgical Reintervention Rate after Prostatic Urethral Lift: Systematic Review and Meta-Analysis Involving over 2,000 Patients. *J Urol*. May 12 2020; 101097JU000000000000001132. PMID 32396049
37. Roehrborn CG. Prostatic Urethral Lift: A Unique Minimally Invasive Surgical Treatment of Male Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. *Urol Clin North Am*. Aug 2016; 43(3): 357-69. PMID 27476128
38. Roehrborn CG, Barkin J, Gange SN, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Can J Urol*. Jun 2017; 24(3): 8802-8813. PMID 28646935
39. Rukstalis D, Grier D, Stroup SP, et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12 month results of the MedLift Study. *Prostate Cancer Prostatic Dis*. Sep 2019; 22(3): 411-419. PMID 30542055
40. Shah BB, Tayon K, Madiraju S, et al. Prostatic Urethral Lift: Does Size Matter?. *J Endourol*. Jul 2018; 32(7): 635-638. PMID 29631445
41. Eure G, Gange S, Walter P, et al. Real-World Evidence of Prostatic Urethral Lift Confirms Pivotal Clinical Study Results: 2-Year Outcomes of a Retrospective Multicenter Study. *J Endourol*. Jul 2019; 33(7): 576-584. PMID 31115257

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Returned to Active Status: 12/01/2020

- 42. Institute for Health and Care Excellence (NICE). Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia [IPG475]. 2014; <https://www.nice.org.uk/guidance/ipg475/chapter/1-recommendations>.
- 43. National Institute for Health and Care Excellence (NICE). UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [MTG26]. 2015; <https://www.nice.org.uk/guidance/mtg26>.

Policy History

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- 10/08/2015 Medical Policy Committee review
- 10/21/2015 Medical Policy Implementation Committee approval. New Policy
- 03/16/2016 Medical Policy Implementation Committee approval. Retired
- 08/06/2020 Medical Policy Committee review
- 08/12/2020 Medical Policy Implementation Committee approval. Brought back to active status. Added “The patient is 45 years of age or older” to criteria.
- 09/03/2020 Medical Policy Committee review
- 09/09/2020 Medical Policy Implementation Committee approval. Repeat procedures explicitly added to the investigational policy statement; statements otherwise unchanged.

Next Scheduled Review Date: 09/2021

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	52441, 52442
HCPCS	C9739, C9740, L8699
ICD-10 Diagnosis	N40.1

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company

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Louisiana

Prostatic Urethral Lift

Policy # 00480

Original Effective Date: 10/21/2015

Current Effective Date: 12/01/2020

Retired Effective Date: 03/16/2016

Returned to Active Status: 12/01/2020

recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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