

Care N' Care Insurance Company of North Carolina, Inc. d/b/a/ HealthTeam Advantage Policy

Medical Policy High intensity focused ultrasound (HIFU) for treatment of prostate cancer			
Department Responsible Utilization Management	Policy Code 9.30	Effective Date 6/14/2018	Next Review Date 6/2023
Title of Person Responsible VP Utilization Management	Approval Council HTA Medical Management Committee		Approved Date 6/13/2018

PURPOSE

This policy should be used to support Healthteam Advantage (HTA) medical necessity coverage guidelines, including documentation requirements for High Intensity Focused Ultrasound. HTA follows medical guidelines such as the national coverage determinations, local coverage determinations, and other manuals for the purpose of determining coverage. This guideline is not a replacement for medical source materials but meant to provide healthplan applications of such.

DEFINITIONS, INITIALS, ACONYMS

High Intensity Focused Ultrasound (HIFU)
NCD – National Coverage Determination
LCD – Local Coverage Determination
CPT – Current Procedural Terminology

POLICY

OVERVIEW

HIFU is now FDA approved treatment modality. Effective January 1, 2021, Medicare and the AMA jointly agreed upon issuing a category 1 CPT code for HIFU treatment (55880) which allows for Physicians, Facilities, and Anesthesiologists to bill for their respective services associated with HIFU treatment.

Medicare has not as yet issued an NCD. The North Carolina LCD has not as yet been issued. In the interim, HTA will adopt National Government Services LCD as our clinical criteria to determine medical necessity.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Whole gland HIFU is considered medically necessary as a local treatment for recurrent PCa following radiation therapy (RT) when ALL of the following criteria are met (1,2):

1. Biochemical recurrence (BCR) according to the Phoenix definition (PSA nadir + 2 ng/mL)
2. Positive post-RT transrectal ultrasound guided (TRUS) biopsy

3. Candidate for local curative therapy as evidenced by favorable clinical and pathologic factors **(BOTH of the following)**
 - a. Original (pre-RT)- clinical stage T1-T2, NX or N0
 - b. Current **(ALL are required)**
 - i. PSA < 10 ng/mL
 - ii. absence of distant metastases per National Comprehensive Cancer Network (NCCN) imaging guidelines
 - iii. no lymph node involvement
 - iv. interval to biochemical failure > 18 months
 - v. International Society of Urological Pathology (ISUP) grade < 4
 - vi. local recurrence amenable to entire destruction
4. Multi-disciplinary consensus (surgeon, oncologist, radiologist)
5. Hi comorbidity (i.e., not a candidate for radical prostatectomy (RP)) (3)

Exclusion Criteria (NONE of the below are allowed)

1. Life expectancy < 10 years (1,2)
2. PCa subtype other than adenocarcinoma (4)
3. Post-RT ADT (5,6)
4. Post-RT anal/rectal stenosis or rectal wall thickness >6 mm by TRUS or MRI (6)

RESPONIBILITIES

The HTA Utilization Management Department has day-to-day responsibility for the operationalization policy and procedures associated with organization determinations for non-emergent out-of-network services, and to ensure that the policy is consistently applied in a uniform manner.

The HTA Medical Management and Quality Council is responsible to ensure that appropriate medical management and quality standards are established and adhered to promote effective and compliant member care.

The HTA Board of Directors have overarching responsibility for review and approval of this policy, and it complies with all applicable federal and state laws, regulations and sub-regulatory guidance.

REFERENCE DOCUMENTS/LINKS

Medicare Managed Care Manual Chapter 13

Code of Federal Regulations: 42 CFR 422.570 and 422.566(b)(3)

National Government Services LCD 38262

NCCN Guidelines – Prostate Cancer Version 2.2019

PREVIOUS REVISION/REVIEW DATES

Date	Reviewed	Revised	Notes
09/07/2018	N/A	N/A	This is a new policy.
06/12/2019	X	X	Approval made by Medical management and Quality Council

02/12/2020	X		Annual review and renewal – no changes made
06/09/2021	X		Annual review and renewal – no changes made
05/11/2022	X	X	Updated to reflect FDA, No NCD, No local LCD. Will utilize National Government Services LCD as our guideline for medical necessity
06/30/2023	X	X	Proposing to retire based on low utilization, providers only taking private pay, and retirement of NGS LCD on which we based this document.