

Medical Coverage Policy

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 1 of 23

Change Summary: Updated Description, Coverage Determination, Coverage Limitations, References, Appendix

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

Disclaimer
Description
Coverage Determination
Background

Medical Alternatives Provider Claims Codes References

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Cryoablation (also known as cryotherapy or cryosurgery) involves the internal or external use of liquid nitrogen or argon gas at extreme cold temperatures to destroy diseased tissue. For external uses, the liquid nitrogen is applied directly with a cotton swab or spray device. For internal purposes, either argon gas or liquid nitrogen is circulated through a cryoprobe that has been situated next to diseased tissue via image guidance, such as ultrasound, magnetic resonance imaging (MRI) or computed tomography (CT), which reportedly ensures less damage to nearby healthy tissue. Ice crystals form around the probe, which freezes the cells. Once the cells thaw, the body absorbs them. Cryoablation may be used to treat several types of cancer including, but may not be limited to, cervical, kidney, liver and prostate. Cryoablation has also been used in precancerous conditions to avoid the development of cancer (eg, cervical intraepithelial neoplasia [CIN]).

Revision Date: 12/08/2021 Review Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 2 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

Cryoablation may be utilized for the treatment of cutaneous (superficial) basal cell carcinoma (BCC) and squamous cell carcinoma in situ (Bowen disease) in which surgery is contraindicated. Choice of treatment depends on factors such as anatomic location, risk factors for tumor recurrence, age and health status of the individual. Cryoablation may purportedly be utilized for the treatment of cutaneous melanoma; however, data appears to be insufficient to support its use for this indication. (Refer to Coverage Limitations section)

Other areas being studied for the use of cryoablation include, but may not be limited to, Barrett's esophagus, bone tumors, breast cancer, breast fibroadenomas, esophageal cancer, pulmonary tumors, non-small cell lung cancer (NSCLC) as well as thyroid cancer. (Refer to Coverage Limitations section)

Cryotherapy is proposed for the use of ocular conditions such as retinal detachment. This treatment is designed to create scar tissue, which will seal the tear or help the retina reattach to the underlying tissue to keep it in the correct position.

Cryotherapy is also being investigated for the treatment of uveal melanoma, retinopathy (eg, diabetic retinopathy) or conjunctival lesions. (Refer to Coverage Limitations section)

Cryoablation is also being investigated for the treatment of chronic rhinitis. The treatment is designed to destroy unwanted tissue and to purportedly interrupt nerve signals in the nose to reduce rhinitis symptoms (eg, ClariFix). (Refer to Coverage Limitations section)

Cryoablation has also been utilized for noncancerous conditions such as atrial fibrillation, benign prostatic hyperplasia, benign skin lesions, chronic nerve pain, chronic spinal pain, plantar fasciitis, uterine fibroids as well as varicose veins.

For information regarding **cryoablation for the treatment of atrial fibrillation (AF)**, please refer to <u>Cardiac Electrophysiological Studies and Cardiac Catheter Ablation</u> Medical Coverage Policy.

For information regarding **cryoablation for benign prostatic hyperplasia**, please refer to <u>Benign Prostatic Hyperplasia</u> (BPH) <u>Treatments</u> Medical Coverage Policy

Revision Date: 12/08/2021 Review Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 3 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

For information regarding **cryoablation for the treatment of benign skin conditions**, please refer to <u>Actinic Keratoses Treatments</u> Medical Coverage Policy and <u>Benign Skin Lesion Treatments</u> Medical Coverage Policy.

For information regarding **cryoablation for chronic nerve and spinal pain**, please refer to <u>Neuroablative Techniques for Chronic Pain</u> Medical Coverage Policy.

For information regarding **cryoablation for the treatment of plantar fasciitis**, please refer to <u>Plantar Fasciitis Treatments</u> Medical Coverage Policy

For information regarding **cryoablation for the treatment of uterine fibroids**, please refer to <u>Uterine Fibroid Surgical Treatments</u> Medical Coverage Policy.

For information regarding **cryoablation for the treatment of varicose veins**, please refer to <u>Varicose Vein Treatments</u> Medical Coverage Policy)

Coverage Determination

Humana members may be eligible under the Plan for **cryoablation** for the following indications:

- Cervical intraepithelial neoplasia (CIN) grade 1, 2 or 3; OR
- Endometrial cryoablation for premenopausal women with menorrhagia (excessive bleeding) not related to uterine fibroids and whom childbearing is complete and are refractory to medical treatment; OR
- Localized, cutaneous (superficial) BCC in which surgery or radiation therapy is contraindicated;⁵⁷ OR
- Localized, cutaneous (superficial) squamous cell carcinoma in situ (Bowen disease) in which surgery is contraindicated;⁶⁷ OR
- Malignant inoperable endobronchial obstruction in symptomatic individuals; OR
- Prostate cancer as a primary therapy alternative to surgery or irradiation in individuals with localized disease (eg, <u>TNM stage</u> T1-T3) OR as salvage therapy for recurrent cancer following failure of radiation therapy; **OR**

Revision Date: 12/08/2021 Review Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 4 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

- Renal cell cancer in individuals who are not candidates for partial nephrectomy, radial nephrectomy or radiofrequency ablation (RFA); OR
- Retinal detachment; OR
- Retinopathy of prematurity; OR
- Soft tissue sarcoma of the extremities or the trunk in symptomatic individuals with disseminated metastases; OR
- Unresectable malignant primary or metastatic liver tumors

Note: The criteria for **cryoablation of the prostate** are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **cryoablation** for any indications other than those listed above including, but may not be limited to:

- Barrett's esophagus; OR
- Bone tumors (primary or metastatic); OR
- Breast cancer; OR
- Breast fibroadenomas; OR
- Chronic rhinitis (eg, ClariFix); OR
- Conjunctival lesions; **OR**
- Cutaneous melanoma; OR
- Diabetic retinopathy; OR

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 5 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

- Esophageal cancer; OR
- Morton's neuromas; OR
- Pancreatic cancer; OR
- Peripheral neuropathy; **OR**
- Plantar fibromas; OR
- Pulmonary tumors (eg, NSCLC); OR
- Thyroid cancer; **OR**
- Uveal melanoma

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Background

Additional information about **cancer**, **menorrhagia**, **retinopathy of prematurity or skin lesions** may be found from the following websites:

- American Academy of Dermatology
- American Academy of Pediatrics
- American Cancer Society
- American College of Obstetricians and Gynecologists
- National Library of Medicine

Medical Alternatives

Alternatives to **cryoablation** include, but may not be limited to, the following:

- Prescription drug therapy
- Radiation
- Surgery

Revision Date: 12/08/2021 Review Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 6 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
17260	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.5 cm or less	
17261	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 0.6 to 1.0 cm	
17262	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 1.1 to 2.0 cm	
17263	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 2.1 to 3.0 cm	
17264	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter 3.1 to 4.0 cm	
17266	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms or legs; lesion diameter over 4.0 cm	
17270	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less	

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 7 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

17271	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 0.6 to 1.0 cm	
17272	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 1.1 to 2.0 cm	
17273	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 2.1 to 3.0 cm	
17274	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter 3.1 to 4.0 cm	
17276	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), scalp, neck, hands, feet, genitalia; lesion diameter over 4.0 cm	
17280	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less	
17281	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.6 to 1.0 cm	
17282	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 1.1 to 2.0 cm	
17283	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 2.1 to 3.0 cm	
17284	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 3.1 to 4.0 cm	

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 8 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

17286	Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter over 4.0 cm	
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma	Not Covered
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation	Not Covered
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)	
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation	Not Covered
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	Not Covered if used to report any treatment outlined in Coverage Limitations section
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	Not Covered if used to report any treatment outlined in Coverage Limitations section
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical	
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed	
50541	Laparoscopy, surgical; ablation of renal cysts	

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 9 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy	
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)	Not Covered if used to report any treatment outlined in Coverage Limitations section
57511	Cautery of cervix; cryocautery, initial or repeat	
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed	
67113	Repair of complex retinal detachment (eg, proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens	
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	
CPT® Category III Code(s)	Description	Comments
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	Not Covered
HCPCS Code(s)	Description	Comments
C2618	Probe/needle, cryoablation	Not Covered if used to report any procedure outlined in Coverage Limitations section

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 10 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral	Not Covered
-------	--	-------------

References

- Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Therapies for clinically localized prostate cancer. http://www.ahrq.gov. Published September 2020. Accessed October 22, 2021.
- Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Treatments for basal cell and squamous cell carcinoma of the skin. http://www.ahrq.gov. Published December 2017. Accessed November 2, 2021.
- 3. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review (ARCHIVED). Local therapies for unresectable primary hepatocellular carcinoma. http://www.ahrq.gov. Published May 2013. Accessed November 2, 2021.
- 4. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review (ARCHIVED). Management of renal masses and localized renal cancer. http://www.ahrq.gov. Published February 2016. Accessed November 2, 2021.
- 5. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review (ARCHIVED). Nonsurgical therapies for stage I and symptomatic obstructive non-small cell lung cancer. http://www.ahrq.gov. Published June 2013. Accessed November 2, 2021.
- 6. American Academy of Allergy, Asthma and Immunology (AAAAI). The diagnosis and management of rhinitis: an updated practice parameter.

 https://www.aaaai.org. Published August 2008. Accessed November 1, 2021.
- 7. American Academy of Dermatology (AAD). Guidelines for the management of cutaneous squamous cell carcinoma. https://www.aad.org. Published March 2018. Accessed October 26, 2021.

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 11 of 23

- 8. American Academy of Dermatology (AAD). Guidelines of care for the management of basal cell carcinoma. https://www.aad.org. Published March 2018. Accessed October 26, 2021.
- American Academy of Ophthalmology (AAO). Preferred Practice Pattern. Posterior vitreous detachment, retinal breaks and lattice degeneration. https://www.aao.org. Published 2014. Updated October 2019. Accessed October 29, 2021.
- American Academy of Pediatrics (AAP). Policy Statement. Screening examination of premature infants for retinopathy of prematurity. https://www.aap.org. Published December 2018. Accessed October 29, 2021.
- 11. American Association for the Study of Liver Diseases (AASLD). Diagnosis, staging and management of hepatocellular carcinoma: 2018 practice guidance by the American Association for the Study of Liver Diseases.

 https://www.aasld.org. Published August 2018. Accessed October 27, 2021.
- 12. American College of Chest Physicians (ACCP). Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. https://www.accp.com. Published May 2013. Updated August 4, 2020. Accessed November 1, 2021.
- American College of Gastroenterology (ACG). ACG clinical guideline: diagnosis and management of Barrett's esophagus. https://gi.org. Published 2015. Accessed October 27, 2021.
- American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin. Endometrial ablation. http://www.acog.org. Published May 2007. Updated 2018. Accessed October 27, 2021.
- American College of Radiology (ACR). Appropriateness Criteria. Radiologic management of hepatic malignancy. https://www.acr.org. Published 2007. Updated 2015. Accessed October 29, 2021.
- 16. American Gastroenterological Association (AGA). American Gastroenterological Association medical position statement on the

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 12 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

management of Barrett's esophagus. https://www.gastro.org. Published March 2011. Accessed October 27, 2021.

- American Radium Society (ARS). ACR Appropriateness Criteria. Locally advanced, high-risk prostate cancer. https://americanradiumsociety.org. Published 1996. Updated 2016. Accessed October 29, 2021.
- 18. American Society for Gastrointestinal Endoscopy (ASGE). Guideline. Endoscopic eradication therapy for patients with Barrett's esophagus-associated dysplasia and intramucosal cancer. https://www.asge.org. Published April 2018. Accessed October 27, 2021.
- American Society for Gastrointestinal Endoscopy (ASGE). Guideline. The role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus. https://www.asge.org. Published 2012. Accessed November 2, 2021.
- American Society for Gastrointestinal Endoscopy (ASGE). Guideline. The role of endoscopy in the assessment and treatment of esophageal cancer. https://www.asge.org. Published 2013. Accessed October 27, 2021.
- American Society of Breast Surgeons (ASBS). Consensus Statement.
 Management of fibroadenomas of the breast.
 https://www.breastsurgeons.org. Published April 29, 2008. Accessed October 27, 2021.
- 22. American Society of Breast Surgeons (ASBS). Consensus statement on the use of transcutaneous and percutaneous ablation for the treatment of benign and malignant tumors of the breast. https://www.breastsurgeons.org. Published October 16, 2018. Accessed October 27, 2021.
- 23. American Society of Clinical Oncology (ASCO). Clinically localized prostate cancer: ASCO clinical practice guideline endorsement of an American Urological Association/American Society for Radiation Oncology/Society of Urologic guideline. https://www.asco.org. Published 2018. Accessed October 27, 2021.

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 13 of 23

- 24. American Thyroid Association (ATA). 2015 American Thyroid Association management guidelines for adult patients with thyroid nodules and differentiated thyroid cancer. https://www.thyroid.org. Published 2016. Accessed October 26, 2021.
- American Thyroid Association (ATA). American Thyroid Association guidelines for management of patients with anaplastic thyroid cancer. https://www.thyroid.org. Published 2012. Accessed October 26, 2021.
- American Thyroid Association (ATA). Revised American Thyroid Association guidelines for the management of medullary thyroid carcinoma. https://www.thyroid.org. Published 2015. Accessed October 26, 2021.
- 27. American Urological Association (AUA). Clinically localized prostate cancer: AUA/ASTRO/SUO guideline. https://www.auanet.org. Published 2017. Accessed November 1, 2021.
- 28. American Urological Association (AUA). Renal mass and localized renal cancer: AUA guideline. https://www.auanet.org. Published April 2017. Updated 2021. Accessed November 1, 2021.
- 29. Centers for Medicare & Medicaid Services (CMS). National coverage determination (NCD) for cryosurgery of prostate (230.9). https://www.cms.gov. Published July 1, 2001. Accessed November 2, 2021.
- 30. ClinicalKey. Chino F, Palta M, Dawson L. Hepatobiliary cancer. In: Tepper JE, Foote RL, Michalski JM. *Gunderson & Tepper's Clinical Radiation Oncology*. Elsevier; 2021:973-994.e6. http://www.clinicalkey.com. Accessed October 26, 2021.
- 31. ClinicalKey. Jayaram P, Yan Y, Mallinson P, Ouellette H, Peter M. Interventional radiologic techniques in the management of bone tumors. In: Heymann D. *Bone cancer*. Elsevier; 2022:807-825. http://www.clinicalkey.com. Accessed October 26, 2021.
- 32. ClinicalKey. Kurup AN, Callstrom MR. Tumor ablation in interventional radiology. In: Tepper JE, Foote RL, Michalski JM. *Gunderson & Tepper's Clinical*

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 14 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

Radiation Oncology. Elsevier; 2021:230-236.e3. http://www.clinicalkey.com. Accessed October 26, 2021.

- 33. ClinicalKey. Yan CH, Hwang PH. Nonallergic rhinitis. In: Flint PW, Francis HW, Haughey BH, et al. *Cummings Otolaryngology: Head and Neck Surgery*, 7th ed. Elsevier; 2021:636-642.e2. http://www.clinicalkey.com. Accessed October 26, 2021.
- 34. ECRI Institute. Clinical Evidence Assessment. ClariFix (Stryker Corp.) for treating chronic rhinitis. https://www.ecri.org. Published September 9, 2020. Accessed October 19, 2021.
- 35. ECRI Institute. Product Brief. Cerene cryotherapy device (Channel Medsystems, Inc.) for treating benign menorrhagia. https://www.ecri.org. Published August 6, 2019. Accessed October 15, 2021.
- 36. ECRI Institute. Product Brief. truFreeze system (CSA Medical, Inc.) for cryosurgical ablation of Barrett's esophagus or esophageal cancer. https://www.ecri.org. Published May 20, 2014. Updated May 2, 2019. Accessed October 15, 2021.
- Hayes, Inc. Clinical Evidence Brief (ARCHIVED). Cryosurgical ablation for malignant endobronchial obstruction (EBO). https://evidence.hayesinc.com.
 Published November 24, 2008. Updated October 29, 2010. Accessed October 19, 2021.
- 38. Hayes, Inc. Evidence Analysis Research Brief (ARCHIVED). Cryotherapy using ClariFix (Arrinex Inc.) for treatment of chronic rhinitis. https://evidence.hayesinc.com. Published October 24, 2019. Updated November 24, 2020. Accessed October 19, 2021.
- 39. Hayes, Inc. Medical Technology Directory. Comparative effectiveness review of cryoablation for primary treatment of localized prostate cancer. https://evidence.hayesinc.com. Published July 27, 2017. Updated September 23, 2020. Accessed October 19, 2021.
- 40. Hayes, Inc. Medical Technology Directory. Comparative effectiveness review of cryoablation for salvage treatment of recurrent prostate cancer following radiotherapy. https://evidence.hayesinc.com. Published January 19, 2007.

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 15 of 23

- Updated January 24, 2011. Updated December 16, 2020. Accessed October 19, 2021.
- 41. Hayes, Inc. Medical Technology Directory (ARCHIVED). Cryoablation for treatment of breast fibroadenomas. https://evidence.hayesinc.com. Published November 7, 2003. Updated January 8, 2008. Accessed October 19, 2021.
- Hayes, Inc. Medical Technology Directory (ARCHIVED). Cryoablation for treatment of non-small cell lung cancer. https://evidence.hayesinc.com. Published December 10, 2015. Updated April 7, 2020. Accessed October 19, 2021.
- 43. Hayes, Inc. Medical Technology Directory (ARCHIVED). Endometrial cryoablation. https://evidence.hayesinc.com. Published November 7, 2003. Updated January 8, 2008. Accessed October 19, 2021.
- 44. Hayes, Inc. Medical Technology Directory (ARCHIVED). Percutaneous cryoablation for the treatment of renal masses.
 https://evidence.hayesinc.com. Published June 9, 2014. Updated May 8, 2018. Accessed October 19, 2021.
- 45. MCG Health. Cryotherapy, cervix. 25th edition. http://www.mcg.com. Accessed October 8, 2021.
- 46. MCG Health. Retinal detachment repair. 25th edition. http://www.mcg.com. Accessed November 2, 2021.
- 47. National Cancer Institute (NCI). Adult primary liver cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated August 23, 2021. Accessed October 28, 2021.
- 48. National Cancer Institute (NCI). Childhood liver cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated October 8, 2021. Accessed October 28, 2021.
- 49. National Cancer Institute (NCI). Colon cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated August 12, 2021. Accessed October 28, 2021.

Revision Date: 12/08/2021 Review Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 16 of 23

- 50. National Cancer Institute (NCI). Non-small cell lung cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated July 12, 2021. Accessed October 28, 2021.
- 51. National Cancer Institute (NCI). Pancreatic neuroendocrine tumors (islet cell tumors) (PDQ) health professional version. http://www.cancer.gov. Updated January 2, 2021. Accessed October 28, 2021.
- 52. National Cancer Institute (NCI). Prostate cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated September 3, 2021. Accessed October 28, 2021.
- 53. National Cancer Institute (NCI). Rectal cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated October 16, 2021. Accessed October 28, 2021.
- 54. National Cancer Institute (NCI). Retinoblastoma treatment (PDQ) health professional version. http://www.cancer.gov. Updated September 21, 2021. Accessed October 28, 2021.
- 55. National Cancer Institute (NCI). Skin cancer treatment (PDQ) health professional version. http://www.cancer.gov. Updated October 8, 2021. Accessed October 28, 2021.
- 56. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Basal cell skin cancer. http://www.nccn.org. Updated February 25, 2021. Accessed October 29, 2021.
- 57. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Bone cancer. http://www.nccn.org. Updated October 8, 2021. Accessed October 29, 2021.
- 58. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Colon cancer. http://www.nccn.org. Updated September 10, 2021. Accessed October 29, 2021.

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 17 of 23

- 59. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Esophageal and esophagogastric junction cancers. http://www.nccn.org. Updated August 3, 2021. Accessed October 29, 2021.
- 60. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Hepatobiliary cancers. http://www.nccn.org. Updated September 21, 2021. Accessed October 29, 2021.
- 61. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Kidney cancer. http://www.nccn.org. Updated September 8, 2021. Accessed October 29, 2021.
- 62. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Neuroendocrine and adrenal tumors. http://www.nccn.org. Updated August 13, 2021. Accessed October 29, 2021.
- 63. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. http://www.nccn.org. Updated October 29, 2021. Accessed October 29, 2021.
- 64. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Prostate cancer. http://www.nccn.org. Updated September 10, 2021. Accessed October 29, 2021.
- 65. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Rectal cancer. http://www.nccn.org. Updated September 10, 2021. Accessed October 29, 2021.
- 66. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Soft tissue sarcoma. http://www.nccn.org. Updated April 28, 2021. Accessed October 29, 2021.
- 67. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Squamous cell skin cancer. http://www.nccn.org. Updated August 16, 2021. Accessed October 29, 2021.

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 18 of 23

- 68. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Thyroid carcinoma. http://www.nccn.org. Updated October 15, 2021. Accessed October 29, 2021.
- 69. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Uveal melanoma. http://www.nccn.org. Updated June 25, 2021. Accessed October 29, 2021.
- 70. Society of Interventional Radiology (SIR). Society of Interventional Radiology multidisciplinary position statement on percutaneous ablation of non-small cell lung cancer and metastatic disease to the lungs. https://sirweb.org. Published August 2021. Accessed November 1, 2021.
- 71. Society of Interventional Radiology (SIR). Society of Interventional Radiology position statement on percutaneous radiofrequency ablation for the treatment of liver tumors. https://sirweb.org. Published July 2009. Accessed November 1, 2021.
- 72. Society of Interventional Radiology (SIR). Society of Interventional Radiology position statement on the role of percutaneous ablation in renal cell carcinoma. https://sirweb.org. Published February 2020. Accessed November 1, 2021.
- 73. UpToDate, Inc. Assessment of tumor response in patients receiving systemic and nonsurgical locoregional treatment of hepatocellular cancer.

 http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 74. UpToDate, Inc. Barrett's esophagus: surveillance and management. http://www.uptodate.com. Updated September 27, 2021. Accessed October 22, 2021.
- UpToDate, Inc. Bronchoscopic cryotechniques in adults.
 http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 19 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

- 76. UpToDate, Inc. Cervical intraepithelial neoplasia: management. http://www.uptodate.com. Updated October 2021. Accessed November 2, 2021.
- 77. UpToDate, Inc. Cryotherapy and other ablative techniques for the initial treatment of prostate cancer. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 78. UpToDate, Inc. Endometrial ablation: non-resectoscopic techniques. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 79. UpToDate, Inc. Image-guided ablation of lung tumors.

 http://www.uptodate.com. Updated September 2021. Accessed October 19, 2021.
- UpToDate, Inc. Image-guided ablation of skeletal metastases.
 http://www.uptodate.com. Updated September 2021. Accessed October 19, 2021.
- 81. UpToDate, Inc. Management and prognosis of the Zollinger-Ellison syndrome (gastrinoma). http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 82. UpToDate, Inc. Management of stage I and stage II non-small cell lung cancer. http://www.uptodate.com. Updated September 28, 2021. Accessed October 22, 2021.
- 83. UpToDate, Inc. Management of superficial esophageal cancer.

 http://www.uptodate.com. Updated October 20, 2021. Accessed October 22, 2021.
- 84. UpToDate, Inc. Medullary thyroid cancer: surgical treatment and prognosis. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 85. UpToDate, Inc. Nonsurgical therapies for localized hepatocellular carcinoma: radiofrequency ablation, laser and microwave thermal ablation, percutaneous injection therapies, cryoablation, high-intensity focused ultrasound and

Revision Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 20 of 23

- irreversible electroporation. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 86. UpToDate, Inc. Nonsurgical therapies for localized hepatocellular carcinoma: Transarterial embolization, radiation therapy and radioembolization. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 87. UpToDate, Inc. Oligometastatic non-small cell lung cancer.
 http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 88. UpToDate, Inc. Overview of benign breast disease. http://www.uptodate.com. Updated September 20, 2021. Accessed October 22, 2021.
- 89. UpToDate, Inc. Overview of endometrial ablation. http://www.uptodate.com. Updated September 16, 2021. Accessed October 22, 2021.
- 90. UpToDate, Inc. Overview of the initial treatment and prognosis of lung cancer. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 91. UpToDate, Inc. Overview of the treatment of renal cell carcinoma. http://www.uptodate.com. Updated October 5, 2021. Accessed October 22, 2021.
- 92. UpToDate, Inc. Overview of therapeutic approaches for adult patients with bone metastasis from solid tumors. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 93. UpToDate, Inc. Overview of treatment approaches for hepatocellular carcinoma. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 94. UpToDate, Inc. Paraganglioma and pheochromocytoma: management of malignant disease. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 21 of 23

- 95. UpToDate, Inc. Radiofrequency ablation and cryoablation for renal cell carcinoma. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 96. UpToDate, Inc. Renal angiomyolipomas. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 97. UpToDate, Inc. Retinal detachment. http://www.uptodate.com. Updated October 2021. Accessed November 3, 2021.
- 98. UpToDate, Inc. Rising serum PSA after radiation therapy for localized prostate cancer: salvage local therapy. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.
- 99. UpToDate, Inc. Surgical treatment and other localized therapy for metastatic soft tissue sarcoma. http://www.uptodate.com. Updated September 2021. Accessed October 22, 2021.

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 22 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

Appendix A

CIN Grades

CIN 1	Abnormal cells are found on the surface of the cervix.
CIN 2	Moderately abnormal cells are found on the surface of the cervix.
CIN 3	Severely abnormal cells are found on the surface of the cervix.

Appendix B

TNM Staging System for Prostate Cancer⁶⁵

Primary tumor (T)		
Clinical T (cT)		
T category	T criteria	
TX	Primary tumor cannot be assessed	
T0	No evidence of primary tumor	
T1	Clinically inapparent tumor that is not palpable	
T1a	Tumor incidental histologic finding in 5% or less of tissue resected	
T1b	Tumor incidental histologic finding in more than 5% of tissue resected	
T1c	Tumor identified by needle biopsy found in one or both sides, but not palpable	
T2	Tumor is palpable and confined within prostate	
T2a	Tumor involves one-half of one side or less	
T2b	Tumor involves more than one-half of one side but not both sides	
T2c	Tumor involves both sides	
Т3	Extraprostatic tumor that is not fixed or does not invade adjacent structures	
T3a	Extraprostatic extension (unilateral or bilateral)	
T3b	Tumor invades seminal vesicle(s)	
T4	Tumor is fixed or invades adjacent structures other than seminal	
	vesicles such as external sphincter, rectum, bladder, levator	
	muscles, and/or pelvic wall.	
Pathological T (pT)		
T category	T criteria	
T2	Organ confined	
Т3	Extraprostatic extension	
T3a	Extraprostatic extension (unilateral or bilateral) or microscopic invasion of bladder neck	

Effective Date: 12/08/2021 Revision Date: 12/08/2021 Review Date: 12/08/2021 Policy Number: HUM-0428-025

Page: 23 of 23

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to Medical and Pharmacy Coverage Policies to verify that this is the current version before utilizing.

T3b	Tumor invades seminal vesicle(s)	
T4	Tumor is fixed or invades adjacent structures other than seminal	
	vesicles such as external sphincter, rectum, bladder, levator	
	muscles, and/or pelvic wall	