Experimental or Investigational

Medical Policy

Utilization Management

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I. DEFINITION:

The use of any service including treatment, procedure, laboratory services, facility, equipment, drug, object, device, or supply, that:

A. Requires approval that has not been granted by the appropriate federal or other governmental agency at the time it is used,
B. Is not yet recognized as acceptable medical practice to treat that illness or injury,
C. Is the subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in FDA regulations, regardless of whether the trial itself is subject to FDA oversight.

Further criteria used in determining whether or not a service is considered experimental or investigational include, but are not limited to:

A. Whether the service is commonly performed or used on a widespread geographic basis,
B. Whether it is generally accepted practice to treat that illness or injury by the medical profession in the United States,
C. Its failure rate and side effects,
D. Whether other, more conventional methods of treating the illness or injury have been exhausted by the participant,
E. Whether it is medically indicated,
F. Whether it is recognized for reimbursement by Medicare

This list should not be considered all-inclusive. The Medical Director or designee may review indications for any technology request on an individual basis for medical necessity and appropriateness, taking into consideration the needs of the individual and the member's

individual policy coverage.

II. MEDICARE ADVANTAGE PLANS:

Prior authorization is recommended as all the drugs, devices and procedures in this policy have been reviewed by the Medical Directors and determined to be Experimental/Investigational based on technology assessments.

Prior authorization is required for all drugs, devices and procedures not included in this policy that may be considered Experimental/Investigational and will be reviewed upon submission of the prior authorization request.

Submit requests through the MyAdvocate Medicare Advantage provider portal located at provider.myadvocatema.com.

Prior Authorization Request form

All requests for either experimental or investigational services shall be reviewed by the Medical Director. The Medical Director shall have the authority to make the final determination if a service is experimental or investigational.

Medicare does not cover items or services considered experimental or investigational, with the exception of routine clinical trial services with dates of service on or after September 19, 2000 that meet the requirements of the Clinical Trials National Coverage Decision (NCD) and are considered reasonable and necessary.

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

Covered services:

A. Digital Breast Tomosynthesis
National Coverage Determination (NCD) for MAMMOGRAMs (220.4)

Medicare Claims Processing Manual: Chapter 18 – Preventive and Screening Services; 20.2.2 – Digital Breast Tomosynthesis

MLN Matters® Number: MM9191

B. Transoral Incisionless Fundoplication (TIF)
Local Coverage Determination (LCD): Select Minimally Invasive GERD Procedures (L35080

C. Leucopatch:
National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3)

D. VectraDA:
LCD – MolDX: Molecular Diagnostic Tests (MDT) (L36807)

E. Acupuncture/dry needling for chronic low back pain is covered beginning 1/21/2020:
Acupuncture (NCD 30.3)
Decision Memo for Acupuncture for Chronic Low Back Pain (CAG-00452N)

F. Genicular nerve block
Local Coverage Determination (LCD) L36850: Peripheral Nerve Blocks
Billing and Coding: Peripheral Nerve Blocks

G. Optune, Tumor Treatment Field Therapy (TTFT)
LCD – Tumor Treatment Field Therapy (TTFT) (L34823) (cms.gov)

H. Bioimpedance spectroscopy (BIS)

I. Proactive and Reactive testing of drug and antibody levels/Therapeutic drug monitoring (TDM)

J. Leqembi to treat Alzheimer's disease **Magellan reviews**

Statement: Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval | CMS

NCD – Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (200.3) (cms.gov)

K. Percutaneous Transluminal Angioplasty (PTA) Concurrent with Carotid Stent Placement
NCD - Percutaneous Transluminal Angioplasty (PTA) (20.7) (cms.gov)

L. Transcarotid Artery Revascularization (TCAR)
Carotid Artery Stenting (CAS) Investigational Studies
NCD 20.7 Percutaneous Transluminal Angioplasty (PTA)
Carotid Artery Stenting (CAS) Investigational Studies | CMS

Noncovered services:

A. Acculink carotid stent when used **without** an embolic protection device.
National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)
"Coverage is limited to procedures performed using an FDA-approved CAS, stents and FDA-approved or -cleared embolic protection devices. The use of an FDA-approved or cleared embolic protection device is required. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is not covered by Medicare."

Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)
"CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible."

B. Heartsbreath
NCD - Heartsbreath Test for Heart Transplant Rejection (260.10) (cms.gov)
Effective for services performed on or after December 8, 2008, the Centers for Medicare & Medicaid Services has determined that the evidence does not adequately define the technical characteristics of the test nor demonstrate that Heartsbreath testing to predict heart transplant rejection improves health outcomes in Medicare beneficiaries. Thus, we conclude that the Heartsbreath test is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act and is non-covered.

C. Barostim Neo – Baroreflex Activation Therapy for Heart Failure

Approved IDE Studies
The following IDE studies have met CMS' standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services. **The list below is NOT all-inclusive. Reference the link below for all IDE Studies.**
Approved IDE Studies | CMS

A. Adult Adipose-Derived Stem Cell Injections Into Partial Thickness Rotator Cuff Tears
NCT Number – NCT02918136
Category – B

B. ELUVIA Drug-Eluting Vascular Stent System
NCT Number – NCT02574481
Category – B

C. EndoVascular Treatment of Acutely Ruptured Shallow Intradural Aneurysms Not Amenable To Clipping And 19Coiling With the Pipeline™ Vantage Embolization Device (VANTAGE)
NCT Number – NCT04391803
Category – B
Pipeline Flex device has been recalled and is no longer commercially available.

D. IN.PACT AV Access Paclitaxel-Coated PTA Balloon Catheter
NCT Number – NCT03041467
Category – B

E. Lariat Suture Delivery Device

NCT Number – NCT04468334
Category – B

F. LINX System for Gastroesophageal REFlux Disease After Laparoscopic Sleeve Gastrectomy
NCT Number – NCT02429830
Category – B

G. MRI/US Fusion Imaging and Biopsy in Combination With Nanoparticle Directed Focal Therapy for Ablation of Prostate Tissue
NCT Number – NCT04240639
Category – A

H. Optune (Tumor Treating Fields, 200kHz) Concomitant With Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma
NCT Number – NCT04471844
Category – B

I. Phasix Mesh
NCT Number – NCT03911700
Category – A

J. Pipeline™ Vantage Embolization Device With Shield Technology™ for Endovascular Treatment of Wide-Necked Intracranial Aneurysms
NCT Number – NCT03873714
Category – B
Pipeline Flex device has been recalled and is no longer commercially available.

K. Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue
NCT Number – NCT03123250
Category – B

Coverage with Evidence Development (CED)
CMS released an updated guidance document on November 20, 2014 that describes coverage with evidence development (CED). CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study. **The list below is NOT all-inclusive. Reference the link below for all CED Studies.**
Coverage with Evidence Development | CMS

A. Allogenic HSCT is only covered pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study with criteria as outlined below for the treatment of the following conditions:
   1. Allogeneic Hematopoietic Stem Cell Transplant for MDS

- Allogeneic Hematopoietic Stem Cell Transplant for MDS | CMS
- NCD – Stem Cell Transplantation (Formerly 110.8.1) (110.23) (cms.gov)
- NCA – Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (CAG-00415N) – Decision Memo (cms.gov)

2. Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma
   - Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma | CMS
   - NCD – Stem Cell Transplantation (Formerly 110.8.1) (110.23) (cms.gov)
   - NCA – Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R) – Decision Memo (cms.gov)

3. Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis
   - Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis | CMS
   - NCD – Stem Cell Transplantation (Formerly 110.8.1) (110.23) (cms.gov)
   - NCA – Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R) – Decision Memo (cms.gov)

4. Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease
   - Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease | CMS
   - NCD – Stem Cell Transplantation (Formerly 110.8.1) (110.23) (cms.gov)
   - NCA – Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R) – Decision Memo (cms.gov)

B. Amyloid PET
   CMS removed NCD 220.6.20 from the Medicare National Coverage Determination (NCD) Manual, effective October 13, 2023. Medicare will follow Commercial coverage.
   - MM13429 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (cms.gov)

C. Autologous Platelet-rich Plasma for Chronic Non-Healing Wounds
   - Autologous Platelet-rich Plasma | CMS
   - N–D - Blood-Derived Products for Chronic Non-Healing Wounds (270.3) (cms.gov)
   - N–A - Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190R–) - Decision Memo (cms.gov)

D. Cochlear Implantation
   - Cochlear Implantation | CMS
   - N–D - Cochlear Implantation (50.3) (cms.gov)
   - N–A - Cochlear Implantation (CAG-00107–) - Decision Memo (cms.gov)

E. Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant
   - Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung

Transplant | CMS
- N–D - Extracorporeal Photopheresis (110.4) (cms.gov)
- N–A - Extracorporeal Photopheresis (ECP) (CAG-00324R–) - Decision Memo (cms.gov)

F. FDG PET and Other Neuroimaging Devices for Dementia
- FDG PET and Other Neuroimaging Devices for Dementia | CMS
- N–D - FDG PET for Dementia and Neurodegenerative Diseases (220.6.13) (cms.gov)
- N–A - Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088–) - Decision Memo (cms.gov)

L. Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management
NCA - Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (CAG-00466N) - Decision Memo
- CardioMEMS HF System NCT06779552
- Cordella Pulmonary Artery Sensor System NCT06783335

G. Leadless Pacemakers
- Leadless Pacemakers | CMS
- N–D - Leadless Pacemakers (20.8.4) (cms.gov)
- N–A - Leadless Pacemakers (CAG-00448–) - Decision Memo (cms.gov)

H. NaF-18 PET for Bone Metastasis
- NaF-18 PET for Bone Metastasis | CMS
- N–D - Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (220.6.19) (cms.gov)

I. Off-label use of Colorectal Cancer Drugs
- Off-label use of Colorectal Cancer Drugs | CMS
- N–A - Anticancer Chemotherapy for Colorectal Cancer (CAG-00179–) - Decision Memo (cms.gov)

J. Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (PILD)/Minimally Invasive Lumbar Decompression (MILD) (Vertos)
- Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis | CMS
- N–D - Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13) (cms.gov)

K. Percutaneous Left Atrial Appendage Closure (LAAC)
- Percutaneous Left Atrial Appendage Closure (LAAC) | CMS
- N–D - Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) (cms.gov)
- N–A - Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445–) - Decision Memo (cms.gov)

L. Pharmacogenomic Testing for Warfarin Response

- Pharmacogenomic Testing for Warfarin Response | CMS
- N–D - Pharmacogenomic Testing for Warfarin Response (90.1) (cms.gov)
- N–A - Pharmacogenomic Testing for Warfarin Response (CAG-00400–) - Decision Memo (cms.gov)

M. TENS for chronic low back pain

- TENS for chronic low back pain | CMS
- N–D - Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27) (cms.gov)

N. Transcatheter Aortic Valve Replacement

- Transcatheter Aortic Valve Replacement | CMS
- N–D - Transcatheter Aortic Valve Replacement (TAVR) (20.32) (cms.gov)
- N–A - Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430–) - Decision Memo (cms.gov)

O. Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation

- Transcatheter Edge-to-Edge Repair (TEER) | CMS
- N–D - Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33) (cms.gov)

P. Transcatheter Mitral Valve Repair (TMVR)

- N–D - Transcatheter Mitral Valve Repair (TMVR) (20.33) (cms.gov)

Q. Transcatheter Tricuspid Valve Replacement (TTVR)- CMS Approval Date: 03/19/2025

- Transcatheter Tricuspid Valve Replacement (TTVR)
- NCA - Transcatheter Tricuspid Valve Replacement (TTVR) (CAG-00467N) - Decision Memo (cms.gov)

R. Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)

- Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) | CMS
- N–D - Vagus Nerve Stimulation (VNS) (160.18) (cms.gov)
- N–A - Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R–) - Decision Memo (cms.gov)

III. COMMENTS:

Experimental/Investigative Services Coding and Packaging Guidelines (For MyAdvocate Medicare Advantage internal use only)

Experimental or Investigational Packaging Table (For MyAdvocate Medicare Advantage internal use only)

IV. REFERENCES:

A. Ablations

1. National Institute for Health and Clinical Excellence (NICE). Percutaneous transluminal renal sympathetic denervation for resistant hypertension. NICE Interventional Procedure Guidance 754. London, UK: NICE; March 2023. https://www.nice.org.uk/guidance/ipg754
2. Clinical Key, Minimally Invasive Techniques for the Management of Thyroid Nodules, Endocrinology and Metabolism Clinics. Baldwin, Chelsey K., MD, ECNU; Natter, Michael B., MD; Published June 1, 2022. Volume 51, Issue 2. Pages 323-349. © 2022.
3. UpToDate. Evaluation of chronic non-cancer pain in adults. www.uptodate.com Last updated: Jan 31, 2024.
4. UpToDate. Approach to the management of chronic non-cancer pain in adults. www.uptodate.com Last updated: Feb 14, 2024.
5. The Association of Extremity Nerve Surgeons. Clinical Practice Guidelines. Denervation. v. 2.0 https://www.aens.us/images/aens/AENS%20CPG%20-%202.0%20-%20FINAL.pdf 2020
6. Hayes, Inc. Health Technology Assessment. Pulsed Radiofrequency for Treatment of Chronic Shoulder Pain. https://evidence.hayesinc.com. Published Sep 30, 2022. Updated Sep 26, 2023.
7. Hayes, Inc. Health Technology Assessment. Pulsed Dye Laser Therapy For Cutaneous Vascular Lesions. https://evidence.hayesinc.com. Published Dec 31, 2012. Updated Dec 1, 2016.
8. UpToDate. Overview of vascular intervention and surgery for vascular anomalies. www.uptodate.com Last updated: Jan 11, 2024.
9. Hayes, Inc. Evolving Evidence Review. RhinAer Procedure (Aerin Medical) for Treatment of Chronic Rhinitis. https://evidence.hayesinc.com. Published Jan 13, 2022. Annual Review: Jan 19, 2024
10. Hayes, Inc. Health Technology Assessment. Radiofrequency Ablation for Benign Thyroid Nodules. https://evidence.hayesinc.com. Published Jun 29, 2021. Updated Jun 13, 2023.
11. UpToDate. Diagnostic approach to and treatment of thyroid nodules. www.uptodate.com Last updated: Nov 07, 2023.
12. ECRI Institute. Clinical Evidence Assessment. Radiofrequency Ablation for Treating Benign Thyroid Nodules. https://www.ecri.org. Published 11/9/2018. Updated 8/30/2021.
13. Hayes, Inc. Health Technology Assessment. Percutaneous Pulsed Radiofrequency for Chronic Postherpetic Neuralgia. https://evidence.hayesinc.com. Published May 5, 2023
14. Hayes, Inc. Health Technology Assessment. Percutaneous Pulsed Radiofrequency for Chronic Cervical Spinal Pain Indications. https://evidence.hayesinc.com. Published May 5, 2023

15. Hayes, Inc. Health Technology Assessment. Pulsed Radiofrequency in Adults for Treatment of Lumbar Facet Joint Pain. https://evidence.hayesinc.com. Published May 5, 2023
16. Hayes, Inc. Health Technology Assessment. Cooled or Pulsed Radiofrequency for Chronic Low Back Pain Arising From the Sacroiliac Joint. https://evidence.hayesinc.com. Published Dec 20, 2022. Annual Review: Dec 22, 2023
17. Hayes, Inc. Health Technology Assessment. Pulsed Radiofrequency Application To The Dorsal Root Ganglion For Treatment Of Lumbosacral Radicular Pain. https://evidence.hayesinc.com. Published May 16, 2019. Annual Review: Jul 6, 2021.
18. Hayes, Inc. Health Technology Assessment. Pulsed Radiofrequency Application To The Dorsal Root Ganglion For Treatment Of Cervical Radicular Pain. https://evidence.hayesinc.com. Published May 3, 2019. Annual Review: Jun 15, 2021.
19. UpToDate. Interventional therapies for chronic pain. www.uptodate.com Last updated: Feb 09, 2024.
20. UpToDate. Brachial plexus syndromes. www.uptodate.com Last updated: Sep 19, 2023.
21. UpToDate. Anterior cutaneous nerve entrapment syndrome. www.uptodate.com Last updated: Sep 27, 2022.
22. UpToDate. Postmastectomy pain syndrome: Risk reduction and management. www.uptodate.com Last updated: Sep 14, 2022.
23. UpToDate. Cervicogenic headache. www.uptodate.com Last updated: Mar 12, 2024.
24. UpToDate. Postherpetic neuralgia. www.uptodate.com Last updated: Oct 25, 2021.
25. ECRI Institute. Clinical Evidence Assessment. Pulsed Field Ablation for Treating Atrial Fibrillation. https://www.ecri.org. Published 5/22/2023. Updated 1/30/2024.
26. Hayes, Inc. Evolving Evidence Review. VivAer (Aerin Medical Inc.) for Nasal Airway Remodeling to Treat Nasal Obstruction. https://evidence.hayesinc.com. Published Jan 13, 2023. Annual Review: Jan 26, 2024.
27. UpToDate. Nasal obstruction: Diagnosis and management. www.uptodate.com Last updated: Nov 22, 2023.
28. ECRI Institute. Clinical Evidence Assessment. Vivaer Nasal Airway Remodeling Stylus (Aerin Medical, Inc.) for Treating Nasal Airway Obstruction. https://www.ecri.org. Published 3/17/2021. Updated 9/14/2022.
29. Hayes, Inc. Evolving Evidence Review. Percutaneous Ultrasonic Tenotomy (Tenex Health TX) for Treatment of Elbow Tendinopathy. https://evidence.hayesinc.com. Published Percutaneous Ultrasonic Tenotomy (Tenex Health TX) for Treatment of Elbow Tendinopathy. Updated Jan 19, 2024.
30. Hayes, Inc. Evolving Evidence Review. Tenex (Tenex Health TX) Percutaneous Ultrasonic Tenotomy System to Treat Achilles Tendinopathy. https://evidence.hayesinc.com. Published Oct 26, 2021. Updated Nov 14, 2023.
31. Hayes, Inc. Evidence Analysis Research Brief. Percutaneous Ultrasonic Tenotomy (Tenex Health TX System) for Treatment of Nonelbow or Non-Achilles Tendinopathy. https://evidence.hayesinc.com. Published Mar 9, 2023.
32. Hayes, Inc. Evidence Analysis Research Brief. Percutaneous Ultrasonic Tenotomy (Tenex

Health TX) for Treatment of Tendinopathy. https://evidence.hayesinc.com. Published Apr 12, 2021.
33. UpToDate. Overview of the management of overuse (persistent) tendinopathy. www.uptodate.com Last updated: Nov 16, 2023.
34. ECRI Institute. Clinical Evidence Assessment. Tenex Health TX System (Tenex Health, Inc.) for Treating Chronic Tendinopathy. https://www.ecri.org. Published 5/22/2013. Updated 3/31/2021.
35. Hayes, Inc. Health Technology Assessment. Conventional Radiofrequency Ablation for Sacroiliac Joint Denervation for Chronic Low Back Pain. https://evidence.hayesinc.com. Published Dec 6, 2022. Updated Dec 28, 2023
36. UpToDate. Subacute and chronic low back pain: Nonsurgical interventional treatment. www.uptodate.com Last updated: May 15, 2024.
37. UpToDate. Interventional therapies for chronic pain. www.uptodate.com Last updated: Apr 16, 2024.
38. Hayes, Inc. Health Technology Assessment. Laser Interstitial Thermal Therapy for Refractory Temporal Lobe Epilepsy. https://evidence.hayesinc.com. Published Feb 19, 2020. Updated Jan 20, 2023.
39. UpToDate. Surgical treatment of epilepsy in adults. www.uptodate.com Last updated: Apr 11, 2024.
40. ECRI Institute. Clinical Evidence Assessment. Laser Interstitial Thermal Therapy for Epilepsy. https://www.ecri.org. Published 9/10/2019. Updated 7/27/2021.
41. Hayes, Inc. Health Technology Assessment. Laser Interstitial Thermal Therapy (LITT) for Treatment of Glioblastoma in Adults. https://evidence.hayesinc.com. Published Sep 20, 2019. Updated Oct 31, 2022.
42. Hayes, Inc. Evidence Analysis Research Brief. Laser Interstitial Thermal Therapy for Recurrent Metastatic Brain Neoplasms. https://evidence.hayesinc.com. Published Aug 3, 2022.
43. Hayes, Inc. Evolving Evidence Review. Laser Interstitial Thermal Therapy for Treatment of Recurrent Metastatic Brain Neoplasms. https://evidence.hayesinc.com. Published Jan 12, 2023. Updated Jan 17, 2024.
44. UpToDate. Management of recurrent high-grade gliomas. www.uptodate.com Last updated: May 28, 2024.
45. UpToDate. Occipital neuralgia. www.uptodate.com Last updated: Feb 27, 2024.
46. ECRI Institute. Clinical Evidence Assessment. Radiofrequency Denervation for Treating Cervical Facet Joint Pain. https://www.ecri.org. Published 9/10/2019. Updated 5/1/2018.
47. Hayes, Inc. Evidence Analysis Research Brief. Thermal Shrinkage for Treatment of Scapholunate Ligament Tears. https://evidence.hayesinc.com. Published Jun 26, 2023
48. UpToDate. Lunate fractures and perilunate injuries. www.uptodate.com Last updated: Jul 26, 2023.
49. UpToDate. Endometriosis: Surgical management of pelvic pain. www.uptodate.com Last updated: Mar 20, 2024.

50. Hayes, Inc. Health Technology Assessment. Farapulse Pulsed Field Ablation System (Boston Scientific Corporation) for Atrial Fibrillation. https://evidence.hayesinc.com. Published Sep 25, 2024
51. Hayes, Inc. Evolving Evidence Review. PulseSelect Pulsed Field Ablation (PFA) System (Medtronic Inc.) for Atrial Fibrillation. https://evidence.hayesinc.com. Published May 30, 2024
52. Hayes, Inc. Emerging Technology Report. Varipulse Pulsed Field Ablation (Biosense Webster Inc.) for Atrial Fibrillation. https://evidence.hayesinc.com. Published Apr 23, 2024
53. Hayes, Inc. Emerging Technology Report. Globe Pulsed Field Mapping and Ablation System (Kardium Inc.) for Atrial Fibrillation. https://evidence.hayesinc.com. Published Dec 21, 2023
54. UpToDate. Overview of catheter ablation of cardiac arrhythmias. www.uptodate.com Last updated: May 13, 2024.
55. UpToDate. Atrial fibrillation: Catheter ablation. www.uptodate.com Last updated: Feb 26, 2024.
56. ECRI Institute. Clinical Evidence Assessment. Pulsed Field Ablation for Treating Atrial Fibrillation. https://www.ecri.org. Published 5/22/2023. Updated 1/30/2024.
57. Hayes, Inc. Health Technology Assessment. Topaz® MicroDebrider (ArthroCare Corp.) for Treatment of Tendon Disorders of the Lower Extremities. https://evidence.hayesinc.com. Published Apr 8, 2011. Updated Mar 29, 2013.
58. Hayes, Inc. Health Technology Assessment. Topaz® MicroDebrider (ArthroCare Corp.) for Treatment of Tendon Disorders of the Upper Extremities. https://evidence.hayesinc.com. Published Mar 31, 2011. Updated Mar 29, 2013.
59. UpToDate. Achilles tendinopathy. www.uptodate.com Last updated: Mar 26, 2025.

B. **Blocks**

1. Hayes, Inc. Evolving Evidence Review. Sphenopalatine Ganglion (SPG) Block for Migraine. https://evidence.hayesinc.com. Published Jul 30, 2021. Updated Mar 29, 2023.
2. UpToDate. Chronic postsurgical pain: Incidence, risk factors, and potential risk reduction. www.uptodate.com Last updated: Mar 07, 2024.
3. UpToDate. Approach to the management of acute pain in adults. www.uptodate.com Last updated: Mar 25, 2024.
4. Hayes, Inc. Health Technology Assessment. Genicular Nerve Block for Treatment of Knee Osteoarthritis. https://evidence.hayesinc.com. Published Dec 7, 2023. Updated Dec 19, 2024.
5. UpToDate. Management of moderate to severe knee osteoarthritis. www.uptodate.com Last updated: Oct 01, 2024.
6. UpToDate. Anesthesia for total knee arthroplasty. www.uptodate.com Last updated: Nov 18, 2024.

C. **BPH Treatments**

1. Hayes, Inc. Evolving Evidence Review. iTind (Olympus) for Benign Prostatic Hyperplasia. https://evidence.hayesinc.com. Published Mar 3, 2022. Annual Review: Mar 15, 2024
2. UpToDate. Surgical treatment of benign prostatic hyperplasia (BPH). www.uptodate.com Last updated: Oct 31, 2023.
3. ECRI Institute. Clinical Evidence Assessment. iTind System (Olympus America, Inc.) for Treating Benign Prostatic Hyperplasia. https://www.ecri.org. Published 3/7/2022. Updated 3/6/2023.
4. Hayes, Inc. Evidence Analysis Research Brief. Optilume Urethral Drug-Coated Balloon (Laborie) for Treatment of Urethral Strictures. https://evidence.hayesinc.com. Published May 10, 2023
5. UpToDate. Strictures of the adult male urethra. www.uptodate.com Last updated: Jul 20, 2023.
6. ECRI Institute. Clinical Evidence Assessment. Optilume Drug-coated Balloon (Urotronic, Inc.) for Treating Urethral Stricture Disease. https://www.ecri.org. Published 3/3/2022. Updated 3/3/2022.

D. **Cardiac**

1. Hayes, Inc. Evidence Analysis Research Brief. Transcatheter Tricuspid Valve Replacement for Tricuspid Valve Failure. https://evidence.hayesinc.com. Published Jun 7, 2023.
2. UpToDate. Management and prognosis of tricuspid regurgitation. www.uptodate.com Last updated: Apr 11, 2023.
3. ECRI Institute. Clinical Evidence Assessment. Percutaneous Tricuspid Valve Replacement for Treating Tricuspid Regurgitation. https://www.ecri.org. Published 1/28/2022.
4. UpToDate. Endovenous intervention for thoracic central venous obstruction. www.uptodate.com Last updated: Apr 26, 2024.
5. UpToDate. Endovenous intervention for iliocaval venous obstruction. www.uptodate.com Last updated: Apr 22, 2024.
6. UpToDate. Malfunction of chronic hemodialysis catheters. www.uptodate.com Last updated: May 08, 2023.
7. ECRI Institute. Clinical Evidence Assessment. Angiovac (AngioDynamics, Inc.) for Treating Deep Vein Thrombosis. https://www.ecri.org. Published 6/30/2022.
8. ECRI Institute. Clinical Evidence Assessment. AngioVac (AngioDynamics, Inc.) for Treating Right-sided Endocarditis. https://www.ecri.org. Published 8/8/2022.
9. Hayes, Inc. Health Technology Assessment. Micra Transcatheter Pacing System (Medtronic Inc.) for Single-Chamber Pacemaker Indications. https://evidence.hayesinc.com. Published Jun 3, 2022. Annual review Jul 9, 2024.
10. Hayes, Inc. . Evidence Analysis Research Brief. Aveir VR Leadless Pacemaker (Abbott) for Single-Chamber Pacemaker Indications. https://evidence.hayesinc.com. Published Mar 6, 2023
11. Hayes, Inc. Clinical Research Response. Leadless Cardiac Pacemakers - Product Comparison. https://evidence.hayesinc.com. Published Jul 26, 2022.

12. Hayes, Inc. Emerging Technology Report. Nanostim Leadless Pacemaker. https://evidence.hayesinc.com. Published Nov 23, 2016.
13. UpToDate. Permanent cardiac pacing: Overview of devices and indications. www.uptodate.com Last updated: Jun 27, 2023.
14. ECRI Institute. Clinical Evidence Assessment. Aveir VR Leadless Pacemaker (Abbott Vascular) for Cardiac Pacing. https://www.ecri.org. Published 5/26/2022.
15. ECRI Institute. Clinical Evidence Assessment. Aveir DR Dual-Chamber Leadless Pacemaker (Abbott Vascular) for Treating Cardiac Arrythmias. https://www.ecri.org. Published 3/29/2024.
16. ECRI Institute. Clinical Evidence Assessment. Micra VR and AV Transcatheter Pacing Systems (Medtronic plc.) for Cardiac Pacing. https://www.ecri.org. Published 4/26/2016. Updated 8/3/2022.
17. Permanent Leadless Cardiac Pacing American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) (Kusumoto et al., 2018)
18. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society American College of Cardiology (ACC), American Heart Association (AHA), and Heart Rhythm Society (HRS) (Kusumoto et al., 2018)
19. Leadless cardiac pacemaker implantation for bradyarrhythmias National Institute for Health and Care Excellence (NICE). 2018 (Interventional procedures guidance, [IPG626]).
20. Hayes, Inc. Health Technology Assessment. CardioMEMS Implantable Hemodynamic Monitor (Abbott) for Managing Patients With Heart Failure. https://evidence.hayesinc.com. Published Jul 28, 2022. Annual Review: Aug 1, 2024
21. UpToDate. Cardiac implantable electronic devices: Periprocedural complications. www.uptodate.com Last updated: Jun 07, 2024.
22. UpToDate. Treatment and prognosis of heart failure with preserved ejection fraction. www.uptodate.com Last updated: Dec 04, 2024.
23. Hayes, Inc. Emerging Technology Report. CyberKnife technology for development of cardiac applications.. https://evidence.hayesinc.com. Published Feb 24, 2011.
24. UpToDate. Electrical storm and incessant ventricular tachycardia. www.uptodate.com Last updated: Feb 25, 2025.
25. ECRI Institute. Stereotactic Body Radioablation for Treating Ventricular Tachycardia Evidence Analysis. https://www.ecri.org. Published 7/26/2021. Updated 7/19/2022.
26. Hayes, Inc. Health Technology Assessment. Left Atrial Appendage Exclusion with the AtriClip System in Patients with Atrial Fibrillation. https://evidence.hayesinc.com. Published Mar 11, 2021. Annual Review: Apr 11, 2024.
27. Hayes, Inc. Health Technology Assessment. Comparative Effectiveness Review of Percutaneous Left Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation. https://evidence.hayesinc.com. Published Feb 13, 2018. Annual Review: Feb 8, 2022.

28. UpToDate. Atrial fibrillation: Left atrial appendage occlusion. www.uptodate.com Last updated: Feb 06, 2025.
29. Hayes, Inc. Health Technology Assessment. Fractional Flow Reserve Testing for Guiding Percutaneous Coronary Interventions (PCIs). https://evidence.hayesinc.com. Published Jul 2, 2013. Annual Review: May 19, 2017.
30. UpToDate. Atrial fibrillation: Clinical use of coronary artery pressure flow measurements. www.uptodate.com Last updated: Nov 07, 2024.

E. **Embolization**

1. Hayes, Inc. Evidence Analysis Research Brief. Genicular Artery Embolization for Treatment of Knee Osteoarthritis. https://evidence.hayesinc.com. Published Aug 28, 2023
2. Hayes, Inc. Health Technology Assessment. Prostatic Artery Embolization for Treatment of Benign Prostatic Hyperplasia. https://evidence.hayesinc.com. Published Apr 25, 2023. Updated Apr 17, 2024
3. UpToDate. Surgical treatment of benign prostatic hyperplasia (BPH). www.uptodate.com Last updated: Jun 26, 2024.
4. ECRI Institute. Clinical Evidence Assessment. Prostate Artery Embolization for Treating Benign Prostatic Hyperplasia. Published 4/25/2019, last updated 9/16/2022.
5. Hayes, Inc. Clinical Research Response. Emborrhoid Procedure for Hemorrhoidal Disease. https://evidence.hayesinc.com. Published Mar 16, 2023.
6. UpToDate. Surgical treatment of hemorrhoidal disease. www.uptodate.com Last updated: Aug 28, 2024.

F. **Grafts**

1. Hayes, Inc. Health Technology Assessment. Processed nerve allografts with the Avance Nerve Graft (Axogen Corporation) for peripheral nerve discontinuities. https://evidence.hayesinc.com. Published March 2, 2020. Updated May 11, 2023.
2. ECRI Institute. Clinical Evidence Assessment. AxoGuard Nerve Protector (AxoGen, Inc.) for Treating Peripheral Nerve Injuries. Published 8/9/2023
3. Cost-Effectiveness of Percutaneous Deep Vein Arterialization for Patients With No-Option Chronic Limb-Threatening Ischemia: An Exploratory Analysis Based on the PROMISE I Study | Journal of CLI Jan B. Pietzsch, PhD1; Merle Ederhof, PhD1; Benjamin P. Geisler, MD, MPH1,2; Peter A. Schneider, MD3 Issue: Vol. 1 - No. 4 - December 2021 ISSN: 2694-3026

G. **Imaging**

1. UpToDate. Breast density and screening for breast cancer. www.uptodate.com Last updated: Aug 04, 2023.
2. NCCN guidelines Version 3.2023 Breast Cancer Screening and Diagnosis. www.nccn.org
3. SMFM CLINICAL GUIDELINE VOLUME 206, ISSUE 4, P300-308, APRIL 2012 MFM Consult Series #52: Diagnosis and management of Fetal Growth Restriction Date posted

December 5, 2020https://www.smfm.org/news/smfm-consult-series-52-diagnosis-and-management-of-fetal-growth-restriction
4. Doppler assessment of the fetus with intrauterine growth restriction Society for Maternal-Fetal Medicine Publications Committee Eliza Berkley, MD, Suneet P. Chauhan, MD, Alfred Abuhamad, MD. DOI:https://doi.org/10.1016/j.ajog.2012.01.022 https://www.ajog.org/article/S0002-9378(12)00051-8/fulltext
5. ACOG PRACTICE BULLETIN Clinical Management Guidelines for Obstetrician–Gynecologists VOL. 137, NO. 2, FEBRUARY 2021

https://files.medelement.com/uploads/materials/f17f05127e54e357c2accd8c6ac8ce6b.pdf

H. **Lithotripsy**

1. Hayes, Inc. Evolving Evidence Review. Intravascular Lithotripsy (IVL) System with C2 Coronary IVL Catheter (Shockwave Medical Inc.) for Calcified Coronary Lesions. https://evidence.hayesinc.com. Published Aug 31, 2021. Annual Review: Jul 20, 2023
2. UpToDate. Specialized revascularization devices in the management of coronary heart disease. www.uptodate.com Last updated: Dec 05, 2023.
3. ECRI Institute. Clinical Evidence Assessment. Shockwave Coronary Intravascular Lithotripsy System (Shockwave Medical, Inc.) for Treating Coronary Artery Disease. https://www.ecri.org. Published 3/16/2021. Updated 2/21/2024.
4. Hayes, Inc. Evolving Evidence Review. Intravascular Lithotripsy for Calcified Peripheral Arterial Lesions. https://evidence.hayesinc.com. Published Nov 19, 2021. Annual Review: Jul 21, 2023
5. UpToDate. Endovascular techniques for lower extremity revascularization. www.uptodate.com Last updated: Aug 15, 2023.
6. ECRI Institute. Clinical Evidence Assessment. Shockwave Peripheral Intravascular Lithotripsy System (Shockwave Medical, Inc.) for Treating Peripheral Artery Disease. https://www.ecri.org. Published 1/13/2017. Updated 5/1/2023.
7. UpToDate. Investigational therapies for treating symptoms of lower extremity peripheral artery disease. www.uptodate.com Last updated: Apr 17, 2024.

I. **Ortho**

1. Hayes, Inc. Evolving Evidence Review. InSpace Biodegradable Subacromial Spacer (Stryker) for Irreparable Rotator Cuff Tears. https://evidence.hayesinc.com. Published Mar 28, 2022. Annual Review: Mar 31, 2023
2. UpToDate. Society guideline links: Shoulder soft tissue injuries (including rotator cuff) - UpToDate. www.uptodate.com
3. ECRI Institute. Clinical Evidence Assessment. InSpace Subacromial Tissue Spacer System (Stryker Corp.) for Treating Massive Rotator Cuff Tears. https://www.ecri.org. Published 9/23/2021. Updated 7/1/2022.
4. UpToDate. Complications of total hip arthroplasty. www.uptodate.com Last updated: Apr 23, 2024.

5. Hayes, Inc. Evolving Evidence Review. Subchondral Calcium Phosphate Injections for Knee Bone Marrow Lesions. https://evidence.hayesinc.com. Published Nov 15, 2021. Annual Review: Nov 1, 2023
6. ECRI Institute. Clinical Evidence Assessment. Subchondroplasty (Zimmer Knee Creations, Inc.) for Minimally Invasive Repair of Knee Bone Marrow Lesions. https://www.ecri.org. Published May 18, 2020 . Updated 6/3/2016.
7. Hayes, Inc. Health Technology Assessment. Concentrated Bone Marrow Aspirate for Spinal Surgery. https://evidence.hayesinc.com. Published Nov 15, 2021. Annual Review: May 8, 2023
8. ECRI Institute. Clinical Evidence Assessment. Bone Marrow Aspirate Concentrate Injection for Treating Knee Osteoarthritis. https://www.ecri.org. Published February 22, 2022.
9. ECRI Institute. Clinical Evidence Assessment. Bone Marrow Aspirate Concentrate Therapy for Achilles Tendinopathy. Published February 15, 2022.
10. ECRI Institute. Clinical Evidence Assessment. Bone Marrow Aspirate Concentrate Therapy for Lumbar Fusion. https://www.ecri.org. Published July 19, 2022.

J. **Pain**

1. Hayes, Inc. Health Technology Assessment. Intravenous Lidocaine Infusion For Neuropathic Pain: A Review Of Reviews. https://evidence.hayesinc.com. Published Apr 20, 2017. Annual Review: Jun 8, 2021
2. UpToDate. Pharmacologic management of chronic non-cancer pain in adults. www.uptodate.com Last updated: Apr 12, 2024.
3. UpToDate. Autoimmune (including paraneoplastic) encephalitis: Clinical features and diagnosis. www.uptodate.com Last updated: Jun 11, 2024.
4. Hayes, Inc. Health Technology Assessment. Pudendal Nerve Block for Treatment of Pudendal Neuralgia. https://evidence.hayesinc.com. Published Jun 22, 2013. Annual Review: May 19, 2015
5. UpToDate. Pudendal and paracervical block - UpToDate. www.uptodate.com Last updated: Oct 04, 2023.
6. UpToDate. Chronic pelvic pain in adult females: Treatment. www.uptodate.com Last updated: Aug 16, 2024.

K. **Nerve Stimulation**

1. Hayes, Inc. Health Technology Assessment. Percutaneous Peripheral Nerve Stimulation for Treatment of Chronic Pain. https://evidence.hayesinc.com. Published May 5, 2022. Updated May 31, 2023.
2. ECRI Institute. Clinical Evidence Assessment. Implantable Peripheral Nerve Stimulation Devices for Treating Chronic Pain. https://www.ecri.org. Published 2/16/2012. Updated 7/28/2023.

L. **Sinus**

1. Hayes, Inc. Evidence Analysis Research Brief. Endoscopic Sinus Surgery With Propel and Propel Mini Bioabsorbable Steroid-Releasing Sinus Implants (Medtronic) in Adults With Chronic Rhinosinusitis. https://evidence.hayesinc.com. Published Nov 27, 2023
2. UpToDate. Chronic rhinosinusitis without nasal polyposis: Management and prognosis. www.uptodate.com Last updated: Apr 11, 2024
3. ECRI Institute. Clinical Evidence Assessment. Propel (Intersect ENT, Inc.) Steroid-eluting Implant for Maintaining Patency after Ethmoid Sinus Surgery. https://www.ecri.org. Published 4/18/2012. Updated 4/21/2021.
4. Hayes, Inc. Health Technology Assessment. Balloon Sinuplasty for Treatment of Chronic Rhinosinusitis in Adult Patients. https://evidence.hayesinc.com. Published Sep 26, 2019. Updated Sep 30, 2022
5. ECRI Institute. Emerging Technology Reports - Evidence Analysis. Standalone Balloon Sinus Dilation for Treating Chronic Rhinosinusitis in Adults. https://www.ecri.org. Published 1/11/2007. Updated 7/20/2016.
6. Hayes, Inc. Health Technology Assessment. Sinuva (Intersect ENT Inc.) Steroid-Releasing Sinus Implant for the Treatment of Nasal Polyps After Ethmoid Sinus Surgery. https://evidence.hayesinc.com. Published Dec 31, 2019. Updated Mar 24, 2023
7. UpToDate. Nasal obstruction: Diagnosis and management. www.uptodate.com Last updated: Mar 22, 2024
8. ECRI Institute. Clinical Evidence Assessment. Sinuva Steroid-eluting Implant (Intersect ENT, Inc.) for Treating Recurrent Nasal Polyps after Ethmoid Sinus Surgery. https://www.ecri.org. Published 4/21/2021.

M. **Syn-One Test**

1. UpToDate. Etiology, clinical manifestations, and diagnosis of vascular dementia. www.uptodate.com Last updated: Apr 24, 2023.

N. **Stent/Balloon catheters**

1. UpToDate. Vertebral artery revascularization. www.uptodate.com Last updated: Sep 15, 2022.
2. Hayes, Inc. Emerging Technology Report. In.Pact Admiral Drug Coated Balloon (DCB) PTA Catheter. https://evidence.hayesinc.com. Published Oct 21, 2015
3. Hayes, Inc. Emerging Technology Report. Lutonix 035 Drug-Coated Balloon (DCB) PTA Catheter. https://evidence.hayesinc.com. Published Jul 2, 2015
4. Hayes, Inc. Emerging Technology Report. Stellarex Drug-Coated Balloon for Peripheral Arterial Disease. https://evidence.hayesinc.com. Published Aug 1, 2017
5. UpToDate. Approach to revascularization for claudication due to peripheral artery disease. www.uptodate.com Last updated: Jan 18, 2024.
6. UpToDate. Management of claudication due to peripheral artery disease. www.uptodate.com Last updated: Oct 02, 2024.
7. UpToDate. Overview of lower extremity peripheral artery disease. www.uptodate.com Last updated: Nov 18, 2024.

8. UpToDate. Endovascular techniques for lower extremity revascularization. www.uptodate.com Last updated: Nov 19, 2024.
9. New Long-Term Data of Paclitaxel Devices Continues to Show No Increased Mortality Compared to Non-Drug Coated Devices | SCAI
10. SCAI Statement on FDA Release of Updated Information on the Use of Paclitaxel-Coated Devices to Treat Peripheral Arterial Disease | SCAI
11. ACC/AHA/SCAI/SIR/SVM 2018 Appropriate Use Criteria for Peripheral Artery Intervention: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, and Society for Vascular Medicine | Journal of the American College of Cardiology
12. Best Practices Documents | Society for Vascular Surgery
13. The Safety of Paclitaxel-Coated Devices for Patients with Peripheral Artery Disease - PMC
14. Benefits and Challenges of Drug-Coated Balloons in Peripheral Artery Disease: From Molecular Mechanisms to Clinical Practice - PMC
15. Paclitaxel-Based Therapies for Patients With Peripheral Artery Disease | Circulation

O. **Transplant Rejection tests**

1. UpToDate. Heart transplantation in adults: Diagnosis of allograft rejection. www.uptodate.com Last updated: Jan 10, 2023.
2. UpToDate. Kidney transplantation in adults: Clinical features and diagnosis of acute kidney allograft rejection. www.uptodate.com Last updated: Jan 16, 2024.
3. UpToDate. Investigational methods in the diagnosis of acute kidney allograft rejection. www.uptodate.com Last updated: Jan 03, 2023.
4. Hayes, Inc. Precision Medicine Research Brief. Prospera Heart (Natera Inc.). https://evidence.hayesinc.com. Published Sep 22, 2023.
5. Hayes, Inc. Precision Medicine Research Brief AlloSure Lung (CareDx). https://evidence.hayesinc.com. Published Aug 4, 2023.
6. Hayes, Inc. Precision Medicine Research Brief. AlloSure Heart (CareDx Inc.). https://evidence.hayesinc.com. Published Sep 19, 2023.
7. Hayes, Inc. Molecular Test Assessment. TruGraf Kidney (Eurofins Transplant Genomics). https://evidence.hayesinc.com. Published Jan 27, 2022. Annual Review: Mar 13, 2024
8. ECRI Institute. Technology News - News. Study suggests biomarkers in urine can predict kidney transplant rejection. https://www.ecri.org. Published 7/19/2013.

P. **Phasix mesh**

Hayes, Inc. Health Technology Assessment. Comparative Effectiveness Review Of Biologic Mesh For Hernia Repair: A Review Of Reviews. https://evidence.hayesinc.com. Published Mar 16, 2018. Updated Mar 1, 2022.

Hayes, Inc. Emerging Technology Report. Phasix Mesh For Hernia Repair.

https://evidence.hayesinc.com. Published Jun 10, 2014.

UpToDate. Hernia mesh. www.uptodate.com Last updated: Apr 24, 2023.

ECRI Institute. Clinical Evidence Assessment. Phasix Mesh (BD) for Hernia and Abdominal Wall Repair. https://www.ecri.org. Published 1/21/2015. Updated 3/15/2023

Q. **Other**

1. UpToDate. Constipation in infants and children: Evaluation. www.uptodate.com Last updated: Nov 27, 2023.
2. UpToDate. Etiology and evaluation of chronic constipation in adults. www.uptodate.com Last updated: Jan 03, 2024.
3. UpToDate. Overview of gastrointestinal motility testing. www.uptodate.com Last updated: Jul 26, 2023.
4. Hayes, Inc. Evolving Evidence Review. Barostim Neo System (CVRx Inc.) for Treatment of Heart Failure. https://evidence.hayesinc.com. Published Nov 7, 2022. Annual Review: Nov 1, 2023.
5. UpToDate. Treatment of resistant hypertension. www.uptodate.com Last updated: Mar 26, 2024.
6. ECRI Institute. Clinical Evidence Assessment. Barostim Neo System (CVRx, Inc.) for Treating Heart Failure. https://www.ecri.org. Published 2/7/2020
7. Hayes, Inc. Health Technology Assessment. Thermal Pulsation for Chronic Dry Eye Syndrome and Meibomian Gland Dysfunction. https://evidence.hayesinc.com. Published Dec 31, 2019. Annual Review: May 2, 2023.
8. UpToDate. Dry eye disease. www.uptodate.com Last updated: Jan 02, 2024.
9. ECRI Institute. Clinical Evidence Assessment. LipiFlow Thermal Pulsation System (TearScience, Inc.) for Treating Dry Eye Syndrome. https://www.ecri.org. Published 10/8/2015. Updated 9/18/2018
10. Hayes, Inc. Health Technology Assessment. Bioelectrical Impedance (Bioimpedance) Analysis for Assessment of Lymphedema. https://evidence.hayesinc.com. Published Dec Aug 6, 2020. Annual Review: Mar 17, 2023.
11. UpToDate. Breast cancer-associated lymphedema. www.uptodate.com Last updated: Jan 02, 2024.
12. UpToDate. Patient survival and maintenance dialysis. www.uptodate.com Last updated: Oct 30, 2023.
13. UpToDate. Lower extremity lymphedema. www.uptodate.com Last updated: Oct 23, 2023.
14. ECRI Institute. Clinical Evidence Assessment. SOZO Bioimpedance Spectroscopy (ImpediMed, Inc.) for Diagnosing and Managing Lymphedema. https://www.ecri.org. Published 5/12/2020.
15. Biogen to Realign Resources for Alzheimer's Disease Franchise | Biogen
16. Hayes, Inc. Health Technology Assessment. Bronchial Thermoplasty for Treatment of Asthma in Adults. https://evidence.hayesinc.com. Published Jul 5, 2022. Annual Review:

Jul 11, 2023.
17. UpToDate. Treatment of severe asthma in adolescents and adults. www.uptodate.com Last updated: May 01, 2024.
18. UpToDate. An overview of asthma management in children and adults. www.uptodate.com Last updated: Apr 10, 2024.
19. ECRI Institute. Clinical Evidence Assessment. Alair Bronchial Thermoplasty System (Boston Scientific Corp.) for Treating Severe Asthma. https://www.ecri.org. Published 4/30/2007. Updated 5/28/2020
20. ECRI Institute. Evidence Reports - Evidence Analysis. Effectiveness and Safety of Bronchial Thermoplasty in Management of Asthma (AHRQ). https://www.ecri.org. Published 12/14/2017.
21. ECRI Institute. Emerging Technology Reports - Evidence Analysis. Bronchial Thermoplasty (Alair System) for Treating Adult Patients with Severe Symptomatic Asthma. https://www.ecri.org. Published 2/14/2011. Updated 10/15/2014.
22. Hayes, Inc. Health Technology Assessment. 3D- Printed Orthopedic Implant. https://evidence.hayesinc.com. Published Jul 5, 2022. Annual Review: Oct 19, 2022.
23. UpToDate. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. www.uptodate.com
24. UpToDate. Management of acute moderate and severe traumatic brain injury. www.uptodate.com Last updated: Aug 13, 2024.
25. UpToDate. Society guideline links: Minor head trauma and concussion. www.uptodate.com
26. ECRI Institute. Clinical Evidence Assessment. BrainScope (BrainScope Co., Inc.) to Aid Diagnosis of Traumatic Brain Injury. https://www.ecri.org. Published 11/9/2020. Updated 11/7/2022.
27. UpToDate. Calcific tendinopathy of the shoulder. www.uptodate.com Last updated: Mar 25, 2024.
28. UpToDate. Kidney stones in adults: Diagnosis and acute management of suspected nephrolithiasis. www.uptodate.com Last updated: May 03, 2024.
29. UpToDate. Kidney stones in children: Prevention of recurrent stones. www.uptodate.com Last updated: Feb 01, 2024.
30. UpToDate. Kidney stones in adults: Prevention of recurrent kidney stones. www.uptodate.com Last updated: Jul 23, 2024.
31. ECRI Institute. Use of Three-dimensional Printed Anatomic Models for Neurologic Surgical Planning. https://www.ecri.org. Published 7/26/2021.
32. ECRI Institute. Use of Three-dimensional Printed Anatomic Models for Cardiovascular Surgical Planning. https://www.ecri.org. Published 7/25/2018. Updated 7/9/2021.
33. ECRI Institute. Use of Three-dimensional Printed Anatomic Models for Orthopedic Surgical Planning. https://www.ecri.org. Published 7/8/2021.
34. ECRI Institute. Full-rotation Three-dimensional Intraoperative Imaging during Spinal Procedures. https://www.ecri.org. Published 9/8/2008. Updated 6/28/2011.
35. Hayes, Inc. Health Technology Assessment. Cardiac Contractility Modulation in Heart

Failure Patients Using the Optimizer Smart System (Impulse Dynamics). https://evidence.hayesinc.com. Published Dec 31, 2019. Annual Review: May 2, 2023.

36. Hayes, Inc. Emerging Technology Report. Optimizer™ III System. https://evidence.hayesinc.com. Published May 27, 2011.
37. UpToDate. Investigational therapies for management of heart failure. www.uptodate.com Last updated: Jun 29, 2022.
38. ECRI Institute. Optimizer Smart System (Impulse Dynamics, Inc.) for Treating Chronic Heart Failure. https://www.ecri.org. Published 12/21/2019. Updated 8/5/2022.
39. Hayes, Inc. Evolving Evidence Review. ReCell Autologous Cell Harvesting Device (Avita Medical) for Treatment of Acute Thermal Burns. https://evidence.hayesinc.com. Published Dec 9, 2022. Annual Review: Dec 17, 2024.
40. UpToDate. Treatment of superficial burns requiring hospital admission. www.uptodate.com Last updated: Mar 02, 2023.
41. UpToDate. Skin autografting. www.uptodate.com Last updated: Oct 28, 2024.
42. Hayes, Inc. Health Technology Assessment. Transoral Incisionless Fundoplication 2.0 With EsophyX (EndoGastric Solutions Inc.) for Treatment of Gastroesophageal Reflux. https://evidence.hayesinc.com. Published May 9, 2023. Annual Review: Jun 14, 2024.
43. UpToDate. Surgical treatment of gastroesophageal reflux in adults. www.uptodate.com Last updated: Sep 27, 2023.
44. Hayes, Inc. Health Technology Assessment. Annular Closure for Prevent of Lumbar Disc Reherniation. https://evidence.hayesinc.com. Published Jun 10, 2024.
45. UpToDate. Clinical features and diagnosis of Alzheimer disease. www.uptodate.com Last updated: Sep 30, 2024.
46. Hayes, Inc. Evolving Evidence Review. IB-Stim (NeurAxis) for Treatment of Pain Associated With Irritable Bowel Syndrome in Adolescents. https://evidence.hayesinc.com. Published July 14, 2022. Annual Review: Jul 17, 2024.
47. Hayes, Inc. Clinical Research Response. IpsiHand (Neurolutions Inc.) https://evidence.hayesinc.com. Published Jan 10, 2025.
48. Hayes, Inc. Evidence Analysis Research Brief. MyoPro Orthosis to Improve Upper Extremity Function and Elbow Range of Motion in Patients with Cerebral Palsy. https://evidence.hayesinc.com. Published Aug 17, 2022.
49. Hayes, Inc. Evidence Analysis Research Brief. Motus Hand and Foot Robotic-Assisted In-Home Devices for Stroke Recovery. https://evidence.hayesinc.com. Published Jun 14, 2024.
50. Hayes, Inc. Health Technology Assessment. Synthetic Tissue for Dural Repair. https://evidence.hayesinc.com. Published Jun 11, 2019.
51. Hayes, Inc. Health Technology Assessment. Bioimpedance Analysis for Assessment of Breast Cancer-Related Lymphedema. https://evidence.hayesinc.com. Published Feb 13, 2025.
52. UpToDate. Clinical features, diagnosis, and staging of peripheral lymphedema. www.uptodate.com Last updated: Feb 04, 2025.
53. UpToDate. Overview of dual-energy x-ray absorptiometry. www.uptodate.com Last

updated: Dec 19, 2023.

54. Hayes, Inc. Evidence Analysis Research Brief. Pressurized Intraperitoneal Aerosol Chemotherapy for Treatment of Peritoneal Carcinomatosis Resulting from Appendiceal Mucinous Adenocarcinoma. https://evidence.hayesinc.com. Published May 14, 2025.
55. Hayes, Inc. Health Technology Assessment. Antibacterial Envelopes for the Prevention of Cardiac Implantable Electronic Device (CIED) Infections. https://evidence.hayesinc.com. Published: May 28, 2020. Annual Review: May 19, 2023.
56. UpToDate. Clinical presentation, course, and prognosis of multiple sclerosis in adults. www.uptodate.com Last updated: Apr 18, 2025.
57. UpToDate. Clinical features and diagnosis of dementia with Lewy bodies. www.uptodate.com Last updated: Oct 30, 2024.
58. UpToDate. Carpal tunnel syndrome: Treatment and prognosis. www.uptodate.com Last updated: Jun 30, 2025.
59. Hayes, Inc. Health Technology Assessment. Endoscopic Surgery for Carpal Tunnel Release: A Review of Reviews. https://evidence.hayesinc.com. Published Apr 6, 2023.
60. Hayes, Inc. Health Technology Assessment. Bioimpedance Analysis for Assessment of Breast Cancer-Related Lymphedema. https://evidence.hayesinc.com. Published Feb 13, 2025.
61. UpToDate. Screening for and prevention of breast cancer-related lymphedema. www.uptodate.com Last updated: Aug 21, 2025.
62. NCCN Guidelines Version 2.2025 Survivorship:
63. Lymphedema . Hayes, Inc. Health Technology Assessment. Use of Anti-infliximab Antibody Levels to Monitor Infliximab Treatment in Patients with Crohn Disease. https://evidence.hayesinc.com. Published Jul 14, 2022. Last updated: Jul 30, 2025
64. UpToDate. Treatment of Crohn disease in adults: Dosing and monitoring of tumor necrosis factor-alpha inhibitors. www.uptodate.com Last updated: Oct 14, 2025