NO. 91117

EXPERIMENTAL / INVESTIGATIONAL / UNPROVEN CARE / BENEFITS EXCEPTIONS

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy defines and addresses experimental, investigational or unproven drugs, devices, treatments, or procedures.

Related policies:

- 91636 – Category III Current Procedural Terminology (CPT®) Codes
- 91448 – Clinical Trials for Self-Funded Groups Opting Out of PPACA
- 91606 – Clinical Trials
- 91447 – Medical Necessity Determination

I. MEDICAL NECESSITY CRITERIA

A. Any drug, device, treatment, or procedure that is experimental, investigational or unproven is considered not medically necessary. A drug, device, treatment, or procedure is experimental, investigational or unproven if any of the following apply:

1. The drug or device final marketing approval or clearance has not been granted by the Food and Drug Administration (FDA); or

2. The drug, device, treatment, or procedure is provided pursuant to oversight by an institutional review board (IRB) or other body that approves or reviews research concerning safety, toxicity or efficacy; or
3. The patient informed consent documents describe the drug, device, treatment, or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity, or efficacy; or
4. Reliable evidence shows that the drug, device, treatment, or procedure is the subject of on-going Phase I or Phase II clinical trials or is the research, experimental, study or investigational arm of on-going Phase III clinical trials; or is otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; or
5. Reliable evidence shows that the prevailing opinion among experts regarding the drug, device, treatment, or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.
6. The drug, device, treatment, or procedure is not widely used or generally accepted as standard medical care for the condition, disease, illness or injury being treated as reported in nationally recognized peer-reviewed medical literature published in the English language.

B. Category III codes: Unless there is a Priority Health Medical Policy or Priority Health Utilization Management delegate medical policy that specifically addresses medical necessity for a particular code, the item, service or procedure represented by any Category III code is considered experimental, investigational, or unproven. See medical policy Category III Current Procedural Terminology (CPT®) Codes #91636.

C. Individual case review may substantiate an exception for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior Plan approval. All determinations for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist.

1. The experimental, investigational, or unproven treatment may be reviewed for exception if the condition is:
    a. A terminal illness, or
    b. A chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.
2. All accepted standard treatments and technologies must be considered or used prior to review for exception under this policy.
3. Any treatment or evaluation (including additional opinions) authorized under this policy must be received at a participating facility or a facility within the Plan's network.
4. Any treatment authorized must be under the auspices of a nationally recognized sponsor such as the National Institutes of Health (NIH) and adhere to the US regulation standards of being approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits.
5. When care is available both within a clinical trial and outside a clinical trial, preference will be given to the clinical trial. When care is available

within multiple trials, preference will be given to the more definitive trial (e.g., Phase III over Phase II).

6. Informed consent must be documented.
7. An independent expert physician review panel may be consulted to determine the appropriateness of the recommended treatment. The panel members will each provide their opinion on whether the treatment is promising and likely to be effective for that individual patient.
8. Costs associated with experimental care: Funding for experimental care, which covers the cost of protocol development and data collection traditionally comes from a variety of sources including pharmaceutical companies, research institutions and government agencies (referred to as "sponsors"). The following is intended to clarify what the plan will reimburse and what the sponsoring facility is expected to cover.
    a. The administrative costs are borne by the facility or sponsor, including:
        i. Data gathering
        ii. Statistical study
        iii. Regulatory requirements
        iv. Contractual agreements
        v. Meetings and travel
    b. The routine patient care costs (conventional care) are borne by Priority Health.
        i. Routine patient care costs are items or services that are typically medically necessary when provided outside a clinical trial or experimental care.
        ii. Routine services include services that would be reimbursable under this policy, even when delivered within the context of a clinical trial or experimental care.
    c. Devices classified under the FDA Investigational Device Exemption (IDE) or Humanitarian Use Device (HUD)/Humanitarian Device Exemption (HDE). See definitions in Description Section & Appendix B.
        i. IDEs
            - Category A IDEs and associated care and services are not medically necessary
            - Category B IDEs when used in a clinical trial and prior authorized by Priority Health:
                - Routine patient care costs in a clinical trial are reimbursable as defined above.
                - The device is not reimbursable

        ii. HUD/HDEs. Devices that have FDA approval for humanitarian use or as HDEs are considered experimental and investigational and excluded from coverage unless they are listed as covered in Appendix C.

d. The costs associated in the delivery of the investigational agent are covered by Priority Health.
    i. Services required solely for the provision of the investigational item shall be provided in accordance with the benefits of the patient's health plan. Coverage would include procedures, drugs or devices approved for coverage for any medical indication.
    ii. The clinically appropriate monitoring of the effects of the item or service should be considered routine patient care costs.
    iii. The prevention of complications of the item or service should be considered routine patient care costs.
    iv. This coverage shall include payment for reasonable and medically necessary services to administer the drug or use the device under evaluation in the clinical trial.
e. Costs incurred for patient care generated specifically by the clinical trial or experimental care shall be borne by the facility or sponsor.
    i. The cost of the investigational drug, device, or service itself.
    ii. Costs incurred for patient care generated specifically by the clinical trial. Examples of these are costs for additional medication, laboratory studies, or diagnostic imaging.
    iii. The health plan's coverage of "routine costs" would not include non-FDA approved drugs or devices or unapproved medical procedures.
    iv. Coverage would not include diagnostic tests that are performed for investigational purposes but not necessary for the member's medical management.
    v. It would also not include services beyond the scope of the member's contract.
f. Costs of treating adverse side effects experienced during treatment are covered by Priority Health. Priority Health will cover medical care needed to treat any complications arising from the experimental and investigational service when the medical services provided are otherwise covered under the member's contract.
g. Care outside the United States is not covered.

Coverage for care and services received in a clinical trial is defined in the Clinical Trials Medical Policy #91606. Refer to the "Clinical Trials" policy for benefits and limitations.

Member must have an advance care planning assessment (see Appendix A at the end of this medical policy) completed by a qualified provider. The assessment should accompany the request for a benefit exception.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Routine Costs in Clinical Trials 310.1	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	*
First Coast Service Options, Inc.	*
Wellpoint Federal (formerly National Government Services, Inc.)	*
Noridian Healthcare Solutions	*
Novitas Solutions, Inc.	*
Palmetto GBA	*
WPS Insurance Corporation	Category III Codes L35490 A56902

*Any NCD or LCD may describe one or more procedures, therapies, interventions, devices, or pharmaceutical agents as experimental and/or investigational broadly or for specific indications.

Medicare Program Integrity Manual, Chapter 13.5.4, Local Coverage. Reasonable and Necessary Provision in an LCD.

Medicare Coverage Related to Investigational Device Exemption (IDE) Studies:

> Approved IDE Studies: The listed 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.

FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions.

III. BACKGROUND

Experimental and investigational (with respect to medical research), refers to a procedure, device or pharmaceutical agent that is still undergoing pre-clinical or clinical evaluation, and/or has not yet received regulatory approval or is not recognized as standard medical care for the condition, disease, illness or injury being treated**.**

Criteria used in determining whether the technologies, equipment, supplies, treatments, procedures, therapies, biologics, drugs, or devices is considered experimental or investigational include, but are not limited to:

1. Whether it is commonly performed or used for the disease or condition;

2. Whether it is generally accepted as standard treatment or diagnosis for the disease or condition by the medical professionals or medical professional societies in the United States;

3. Whether it is medically indicated;

4. Whether there is sufficient or conclusive data to assess the therapeutic value or positive effects on short and long-term health outcomes (e.g., safety and effectiveness, failure rate, and side effects)

Medical research is conducted to aid the body of knowledge in the field of medicine. This can be divided into two general categories: New treatments that are tested in clinical trials, and all other research contributing to the development of new treatments. A new treatment refers to any form of previously untested treatment for a particular pathology. This can take the form of a new surgical procedure, a new drug, or a new treatment regimen. These are extensively tested in clinical trials prior to wide-spread use. Formal clinical trials have, among other aspects, extensive written research protocols that adhere to established research principles and study design.

At the early stages, study protocols usually focus on the safety of the new drug, device, or procedure using a single group of research subjects. Such “single arm” trials generally are followed by more extensive studies that measure the experimental intervention against alternative therapies and/or involve a rudimentary comparison between experimental and control subject groups. When basic **s**afety and efficacy have been demonstrated by the experimental scientific process the investigational phase begins. As the research further matures, the new intervention will be tested in double-blind randomized studies, the so-called “gold-standard” of research. Depending on study results, the intervention may become a generally recognized standard of care.

The FDA defines Humanitarian Use Device (HUD) as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year. Humanitarian Device Exemption (HDE) is a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions. HDE approval authorizes marketing of an HUD device for its specified indication for use. HDE approval is based upon, among other criteria, a determination by the FDA that the HUD will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use (while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment). The law exempts HDE devices from demonstrating a reasonable assurance of effectiveness, and instead requires demonstration of probable benefit. This difference in

determination of effectiveness is a key difference between applications for premarket approval (PMA) and HDE devices. The table below compares some key aspects of HDEs and PMAs.

Definitions:

Clinical Trials (*from the National Cancer Institute*)

Clinical trials in cancer therapy are conducted to decrease morbidity and mortality from cancer. New drug development is one part of this effort, but other parts include the integration of multiple treatment modalities, the testing of new combinations of existing drugs, the testing of new dose schedules and routes of administration, the application of new diagnostic tests in choosing treatment regimens, and the evaluation of supportive care methods.

> *Phase I* — The initial clinical test of a new treatment modality. Most Phase I patients have cancer for which no other effective therapeutic options are known, and patients with any type of cancer are admitted to most Phase I trials.
>
> *Phase II* — The initial efficacy trial of a new cancer agent. The trial is done on groups of patients with one type of cancer.
>
> *Phase III* — Designed to compare one or more treatments. A new drug or drug combination ("research arm") may be tested against a drug combination of proven efficacy. The patients are randomly allocated to the treatment options.

Clinical Trials for Investigational New Drugs (*from the Food & Drug Administration*)

> *Phase I* — Testing concerned primarily with the safety of the drug and normally done on a small number (20-100) of healthy volunteers.
>
> *Phase II* — This phase of drug testing involves a few hundred patients and is designed to show whether the drug is effective in treating the disease or condition for which it is intended. Most Phase II studies are randomized controlled trials.
>
> *Phase III* — The population size is expanded to several hundred to several thousand to clarify the drug's benefit-risk relationship and discover side effects and adverse reactions.
>
> These three phases are necessary for FDA marketing approval of a new drug. Post marketing surveillance (*Phase IV*) is done to detect adverse reactions that might not have been detected in earlier trials.

Current Procedural Terminology (CPT®) Category III codes: Developed by the American Medical Association (AMA) and defined as a set of temporary (“T”) codes that allow data collection for emerging technologies, services, procedures, and service paradigms. These codes are intended to be used for data collection to substantiate widespread usage or to provide documentation for the Food and Drug Administration (FDA) approval process. Unlike Category I CPT® codes, the procedures and services described by Category III CPT® codes do not necessitate FDA approval and therefore have been placed in a separate section of the CPT book. Per the AMA, “the inclusion of a service or procedure in this section does not constitute a

finding of support, or lack thereof, with regard to clinical efficacy, safety, applicability to clinical practice, or payer coverage." The Category III CPT® Code description does not establish a service or procedure as safe, effective or applicable to the clinical practice of medicine.

Investigational Device Studies (IDEs)

> Category A (Experimental) device refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.
>
> Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

Peer-reviewed literature – Articles or reports that have gone through an evaluation process in which journal editors and other expert scholars critically assess the quality and scientific merit of the article and its research. Articles that pass this process are published in the peer-reviewed literature. Peer-reviewed journals may include the research of scholars who have collected their own data using an experimental study design, survey, or various other study methodologies. They also present the work of researchers who have performed novel analyses of existing data sources, such as the ones described in this section.

Peer-reviewed literature is accessible via academic databases that enable users to execute searches across multiple journals.

Promising — Preliminary scientific data supports reasonable likelihood of success of the treatment for the diagnosis.

Reliable evidence means published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, treatment or procedure.

Terminal illness — A disease that can be expected to result in death within 1 year in the absence of effective treatment.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
Social Security Administration (SSA)	(SSA §1862(a)(1)(A)) EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER (SSA §1862(a)(1)(A))
American Medical Association (AMA)	REPORT 03 OF THE COUNCIL ON MEDICAL SERVICE (A-23) Private Insurer Payment Integrity

	(Reference Committee A) (Jeffers L, 2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information. Specifically:

Humanitarian Device Exemption (HDE)

Listing of CDRH Humanitarian Device Exemptions Database

HDE Database

HDE Approvals

Investigational Device Exemption (IDE)

VI. CODING

See Policies:
91448 Clinical Trials for Self Funded Groups Opting Out of PPACA
91606 Clinical Trials
91636 Category III Current Procedural Terminology (CPT®) Codes

NOT MEDICALLY NECESSARY: services based on Experimental, Investigational, Unproven Care and plan document language. *This List is not inclusive. These codes are not included in any specific medical policy.*

CPT/HCPCS Codes
20560 Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561 Needle insertion(s) without injection(s); 3 or more muscles

34839 Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time

53451 Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
53452 Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance
53453 Periurethral transperineal adjustable balloon continence device; removal, each balloon
53454 Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume

83876 Myeloperoxidase (MPO)

84393 Tau, phosphorylated (eg, pTau 181, pTau 217), each

84394 Tau, total (tTau)
84431 Thromboxane metabolite(s), including thromboxane if performed, urine

87513 Infectious agent detection by nucleic acid (DNA or RNA); Helicobacter pylori (H. pylori), clarithromycin resistance, amplified probe technique

90865 Narcosynthesis for psychiatric diagnostic and therapeutic purposes (eg, sodium amobarbital (Amytal) interview)

91117 Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, e.g., meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report

92145 Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report

93895 Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

99026 Hospital mandated on call service; in-hospital, each hour
99027 Hospital mandated on call service; out-of-hospital, each hour
99070 Supplies and materials (except spectacles), provided by the physician or other qualified health care professional over and above those usually included with the office visit or other services rendered (list drugs, trays, supplies, or materials provided)
99071 Educational supplies, such as books, tapes, and pamphlets, for the patient's education at cost to physician or other qualified health care professional
99072 Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other nonfacility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease
99075 Medical testimony
99080 Special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting form
99082 Unusual travel (e.g., transportation and escort of patient)

A4341 Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342 Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4563 Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each
A6590 External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591 External urinary catheter; non-disposable, for use with suction pump, per month
A9291 Prescription digital behavioral therapy, FDA-cleared, per course of treatment

A9292 Prescription digital visual therapy, software-only, fda cleared, per course of treatment

C1600 Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)
C1603 Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)
C1604 Graft, transmural transvenous arterial bypass (implantable), with all delivery system components
C1741 Anchor/screw for bone fixation, absorbable (implantable)
C1824 Generator, cardiac contractility modulation (implantable)
C1982 Catheter, pressure-generating, one-way valve(e.g., one-way valve, intermittently occlusive)

C8004 Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors
C8006 Insertion of pleural-peritoneal shunt with intercostal pump chamber, including imaging, injection(s) of contrast with radiological supervision and interpretation, when performed
C8014 Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)

C9759 Transcatheter intraoperative blood vessel microinfusion(s) (e.g., intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed
C9760 Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
C9782 Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study
C9783 Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catherization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (IDE) study
C9796 Repair of enterocutaneous fistula small intestine or colon (excluding anorectal fistula) with plug (e.g., porcine small intestine submucosa [sis])
C9797 Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all

radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction

E0490 Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491 Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0677 Nonpneumatic sequential compression garment, trunk

G0183 Quantitative software measurements of cardiac volume, cardiac chambers volumes and left ventricular wall mass derived from ct scan(s) data of the chest/heart (with or without contrast)
G0219 PET imaging whole body; melanoma for noncovered indications
G0235 PET imaging, any site, not otherwise specified
G0252 PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
G0429 Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
G0513 Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service)
G0514 Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service)
G0516 Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant)
G0517 Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)
G0518 Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants)
G0561 Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral
G0685 Algorithmic analysis for identification of new lesions and determination of change of existing lesions for advanced metastatic cancer using data sets from two or more previously acquired pet or pet/ct studies
G9147 Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration

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J7318 – J7329 Hyaluronic acid derivatives

J8670 Rolapitant, oral, 1 mg

K1007 Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors
K1030 External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only
K1035 Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared

Q2026 Injection, Radiesse, 0.1 ml
Q2028 Injection, sculptra, 0.5 mg
0002U Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps
0021U Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'- UTR-BMI1, CEP 164, 3'-UTRRopporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score
0024U Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative
0025U Tenofovir, by liquid chromatography with tandem mass spectrometry (LC-MS/MS), urine, quantitative
0035U Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking induced conformational conversion, qualitative
0039U Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity
0041U Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM
0042U Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG
0043U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM
0044U Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG
0058U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative
0059U Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative
0061U Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis
0062U Autoimmune (systemic lupus erythematosus) IgG and Igm analysis of 80 biomarkers, utilizing serum, and algorithm reported with a risk score
0063U Neurology (autism), 32 amines by LCMS/MS, using plasma, and algorithm reported as metabolic signature associate with autism spectrum disorder
0064U Antibody, Treponema pallidum, total and rapid plasma regain (RPR), immunoassay, qualitative
0065U Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)

0077U Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype
0080U Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
0083U Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
0091U Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result
0092U Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
0093U Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected
0095U Eosinophilic esophagitis, 2 protein biomarkers (Eotaxin-3 [CCL26 {C-C motif chemokine ligand 26}] and Major Basic Protein [PRG2 {proteoglycan 2, pro eosinophil major basic protein}]), enzyme-linked immunosorbent assays (ELISA), specimen obtained by esophageal string test device, algorithm reported as probability of active or inactive eosinophilic esophagitis
0096U Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine
0105U Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)
0106U Gastric emptying, serial collection of 7 timed breath specimens, non-radioisotope carbon-13 (13C) spirulina substrate, analysis of each specimen by gas isotope ratio mass spectrometry, reported as rate of 13CO2 excretion
0109U Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species

0119U Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events
0121U Sickle cell disease, microfluidic flow adhesion (VCAM-1), whole blood
0122U Sickle cell disease, microfluidic flow adhesion (P-Selectin), whole blood
0123U Mechanical fragility, RBC, shear stress and spectral analysis profiling
0140U Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected
0141U Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target),

blood culture, amplified probe technique, each target reported as detected or not detected

0142U Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected

0174U Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents

0206U Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease

0207U Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)

0210U Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)

0303U Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; hypoxic

0304U Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; normoxic

0305U Hematology, red blood cell (RBC) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index

0312U Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment

0316U Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine

0322U Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD

0337U Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization, and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood

0338U Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker-expressing cells, peripheral blood

0342U Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline

0344U Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH

0358U Neurology (mild cognitive impairment), analysis of B-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative

0360U Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy

0361U Neurofilament light chain, digital immunoassay, plasma, quantitative

0365U Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer

0367U Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection

0385U Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease

0387U Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin-fixed paraffin-embedded (FFPE) tissue, report for risk of progression

0390U Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score

0393U Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative

0399U Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgG-binding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected

0404U Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression

0406U Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer

0412U Beta amyloid, AB42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology

0431U Glycine receptor alpha1 IgG, serum or cerebrospinal fluid (CSF), live cell-binding assay (LCBA), qualitative

0432U Kelch-like protein 11 (KLHL11) antibody, serum or cerebrospinal fluid (CSF), cell-binding assay, qualitative

0435U Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations
0436U Oncology (lung), plasma analysis of 388 proteins, using aptamer-based proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy
0445U B-amyloid (Abeta42) and phospho tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0446U Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity
0447U Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare
0457U Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative
0458U Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
0459U β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
0462U Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary
0468U Hepatology (nonalcoholic steatohepatitis [NASH]), miR-34a5p, alpha 2-macroglobulin, YKL40, HbA1c, serum and whole blood, algorithm reported as a single score for NASH activity and fibrosis
0472U Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semiqualitative, blood, reported as predictive evidence of early Sjögren syndrome
0479U Tau, phosphorylated, pTau217
0482U Obstetrics (preeclampsia), biochemical assay of soluble fmslike tyrosine kinase 1 (sFlt-1) and placental growth factor (PlGF), serum, ratio reported for sFlt1/PlGF, with risk of progression for preeclampsia with severe features within 2 weeks
0503U Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (ptau217, nptau217, ptau217/nptau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as likelihood of positive or negative for amyloid plaques
0521U Rheumatoid factor IgA and IgM, cyclic citrullinated peptide (CCP) antibodies, and scavenger receptor A (SR-A) by immunoassay, blood
0522U Carbonic anhydrase VI, parotid specific/secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies immunoassay, semiqualitative, blood
0524U Obstetrics (preeclampsia), sFlt1/PlGF ratio, immunoassay, utilizing serum or plasma, reported as a value

0525U Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug
0526U Nephrology (renal transplant), quantification of CXCL10 chemokines, flow cytometry, urine, reported as pg/mL creatinine baseline and monitoring over time
0535U Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0545U Acetylcholine receptor (AChR), antibody identification by immunofluorescence, using live cells, reported as positive or negative
0546U Low-density lipoprotein receptor-related protein 4 (LRP4), antibody identification by immunofluorescence, using live cells, reported as positive or negative
0547U Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative
0548U Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma
0550U Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer
0551U Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma
0559U Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression
0568U Neurology (dementia), beta amyloid (AB40, AB42, AB42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology
0570U Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison
0573U Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous
0579U Nephrology (diabetic chronic kidney disease), enzyme-linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline
0584U Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative
0589U Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0591U Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins

and digital rectal examination, results reported as a probability score for clinically significant prostate cancer

0596U Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LC-MS/MS), reported as an APOE prototype

0598U Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by enzyme-linked immunosorbent assay (ELISA), whole blood or serum, report as elevated (positive) or normal (negative) antibody levels

0599U Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative

0636U Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG

0637U Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM

0638U Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG

0639U Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.

- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

1. National Library of Medicine. Health Data Sources. Peer-reviewed Literature.

SUMMARY OF CHANGES

No changes to medical necessity criteria.

Past committee review dates: 01/1993, 04/1995, 10/1997, 04/1999, 02/2001, 12/2001, 11/2002, 11/2003, 11/2004, 10/2005, 10/2006, 10/2007, 10/2008, 04/2009, 04/2010, 04/2011, 04/2012, 04/2013, 12/2013, 11/2014, 11/2015, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 05/2022, 05/2023, 05/2024, 05/2025, 05/2026

APPENDIX A

ADVANCE CARE PLANNING ASSESSMENT

1. **Medical history and reason for referral:**
2. **Patient's understanding of current disease status and overall prognosis:**

   Medical care options discussed with patient:
3. **Has patient completed an Advance Care Planning conversation, including designation of patient advocate as part of the advance directive, with a certified ACP facilitator*? Yes ☐ No ☐ If no, answer questions 4-9. If yes, this form is complete.**
4. **What are patient's wishes/goals for remainder of life (quality of life vs. length of life; importance of physical comfort; how patient wishes to spend time, etc.)?**
5. **How does patient describe their current physical/mental symptoms? What is quality of life rating using QOL, HR QOL scale, SF 36 (short-form health questionnaire)?**
6. **Spiritual or cultural beliefs related to illness and death that would affect enrollment? Yes ☐ No ☐**
7. **Is advance directive complete? Yes ☐ No ☐**

   (i.e. Making Choices Michigan)
8. **Patient has designated a durable power of attorney for healthcare? Yes ☐ No ☐**
9. **Does family/patient advocate support patient's preference for medical care as outlined in advance directive? Yes ☐ No ☐**

***Certified ACP facilitators are trained through the Respecting Choices® curriculum. Trained facilitators are available at health systems, Making Choices Michigan, and community organizations.**

APPENDIX B

CLINICAL TRIALS COVERAGE REFERENCE SHEET***

	Commercial Fully-funded	**Commercial Self-funded**	**Medicare**
Clinical Trials	Routine services* only, use *Clinical Trials Policy #91606*	Non-grandfathered groups: routine services only, use *Clinical Trials Policy #91606* Grandfathered groups opting out of PPACA: use *Clinical Trials for Self Funded groups opting out of PPACA #91448*	Original Medicare covers routine services for those trials that are Medicare approved If trial is not Medicare approved, there is no coverage under Original Medicare or Priority Health Medicare.
IDE (Investigational Device Exemption) Trial: Category A Device	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117*	Never covered. Device and all services, including routine services, are not covered. Use *Experimental & Investigational Policy #91117*	Device is never covered. Routine care items and services in CMS-approved Category A IDE studies are covered by Priority Health Medicare
IDE Trial: Category B Device	Routine services only; device not covered.** Use *Experimental & Investigational Policy #91117*	Device and all services, including routine services, are not covered.** Use *Experimental & Investigational Policy #91117*	All services, including the device, are covered by Priority Health Medicare
Clinical Studies Approved Under Evidence Development (CED)	Use *Experimental & Investigational Policy #91117* to determine coverage	Use *Experimental & Investigational Policy #91117* and individual plan documents to determine coverage	All care and services are covered by Priority Health Medicare

*Routine patient care costs are items or services that are typically covered benefits when provided outside a clinical trial. The clinical trial protocol may be needed to determine the specific services that are covered and excluded.

**Priority Health may, at its discretion, choose to cover the experimental device if the cost of that device is less than the non-experimental arm of the trial.

***For Medicaid/Healthy Michigan refer to Section III “Application to Products”

APPENDIX C

HUMANITARIAN USE DEVICE (HUD)/ HUMANITARIAN DEVICE EXEMPTION (HDE) REFERENCE SHEET

The following HUDs/HDEs may be covered when used in accordance with their FDA approval

HUD/HDE Covered Devices	Medical Policy Supporting Coverage
1. Activa Dystonia Therapy (Medtronic)	Stimulation Therapy and Devices medical policy #91468
2. Impella circulatory assistance	Ventricular Assist Devices medical policy #91509
3. Enterra Therapy System	Gastroparesis Testing and Treatment medical policy #91572
4. Epicel (cultured epidermal autografts)	Skin Substitutes and Soft Tissue Grafts medical policy #91560
5. INTACS for keratoconus	Vision Care medical policy #91538
6. NeuRX diaphragmatic stimulator for spinal cord injury	Stimulation Therapy and Devices medical policy #91468

Note: Devices that have FDA approval for humanitarian use or as HDEs are considered experimental and investigational and excluded from coverage unless they are listed above.

The FDA list of HDEs can be found at https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions (Accessed April 10, 2026)

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