United Healthcare Medicare Advantage

UnitedHealthcare Medicare Advantage
Policy Guideline Update Bulletin: May 2022

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Policy Title	**Approval Date**	**Summary of Changes**
Clinical Diagnostic Laboratory Services	Apr. 13, 2022	**Related Policies** • Added reference link to the Medicare Advantage Reimbursement Policy titled *Molecular Pathology Policy, Professional and Facility* **Applicable Codes** • Added CPT codes 0306U, 0307U, 0308U, 0309U, 0310U, 0311U, 0312U, 0313U, 0314U, 0315U, 0316U, 0317U, 0318U, 0319U, 0320U, 0321U, 0322U, and 87563 • Removed CPT code 0119U, 0227U, 0285U, 0286U, 0287U, 0288U, 0289U, 0290U, 0291U, 0292U, 0293U, 0294U, 0296U, 0297U, 0298U, 0299U, 0300U, 81349, 81513, 81514, 81523, 87154, 87483, and 87625 • Added notation to indicate ICD-10 diagnosis code Z36.89 is excluded from non-coverage for CPT codes 86790 and 86794 when reported for Zika Virus Testing by PCR and ELISA Methods **Supporting Information** • Updated *References* section to reflect the most current information

Extracorporeal Photopheresis (NCD 110.4)	Apr. 13, 2022	**Related Policies**
		• Added reference link to the:
		  ○ Medicare Advantage Policy Guideline titled *Routine Costs in Clinical Trials (NCD 310.1)*
		  ○ Medicare Advantage Coverage Summary titled *Experimental Procedures and Items, Investigational Devices and Clinical Trials*
		Questions and Answers (Q&A)
		• Updated Q&A pertaining to CPT/HCPCS codes with limited coverage under CED (Coverage with Evidence Development)
		Supporting Information
		• Updated *References* section to reflect the most current information

Genetic Testing for Lynch Syndrome	Apr. 13, 2022	**Applicable Codes** ***Diagnosis Codes*** **For CPT codes 81292, 81293, and 81294** • Added C56.3, Z85.030, and Z85.040 **Supporting Information** • Updated *References* section to reflect the most current information
Histocompatibility Testing (NCD 190.1)	Apr. 13, 2022	**Related Policies** • Removed reference link to the Medicare Advantage Policy Guideline titled *Clinical Diagnostic Laboratory Services* **Supporting Information**

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Histocompatibility Testing (NCD 190.1) (continued)	Apr. 13, 2022	• Updated *References* section to reflect the most current information

Self-Administered Drug(s) (SAD)	Apr. 13, 2022	Applicable Codes
		• Updated list of applicable drug names:
		  ○ For HCPCS code C9399:
		  ▪ Added:
		  – Risankizumab-Rzaa (Skyrizi™)
		  – Ropeginterferon Alfa-2b-Njft (Besremi)
		  ▪ Removed:
		  – Abatacept SQ (Orencia®)
		  ○ For HCPCS codes J3490, J3590, and J9999:
		  ▪ Added:
		  – Ropeginterferon Alfa-2b-Njft (Besremi)
		  ▪ Removed:
		  – Abatacept SQ (Orencia®)
		Supporting Information
		• Updated *References* section to reflect the most current information

Vaccination (Immunization)	Apr. 13, 2022	Applicable Codes *Tetanus-Diphtheria* • Added ICD-10 diagnosis codes S02.413B, S12.030B, S12.031B, S12.34XB, S12.350B, S12.351B, S12.390B, S12.391B, S12.64XB, S12.650B, S21.431A, S21.431D, S21.432A, S21.432D, S22.030B, S22.031B, S22.032B, S22.038B, S22.23XB, S22.31XB, S22.32XB, S22.43XB, S32.010B, S32.011B, S32.012B, S32.018B, S32.020B, S32.021B, S32.022B, S32.028B, S32.030B, S32.031B, S32.032B, S32.038B, S32.040B, S32.041B, S32.042B, S32.048B, S32.050B, S32.051B, S32.052B, S32.058B, S32.110B, S32.111B, S32.112B, S32.120B, S32.121B, S32.122B, S32.130B, S32.131B, S32.132B, S32.14XB, S32.15XB, S32.16XB, S32.17XB, S32.19XB, S32.2XXB, S32.311B, S32.312B, S32.314B, S32.315B, S32.391B, S32.392B, S32.411B, S32.412B, S32.414B, S32.415B, S32.421B, S32.422B, S32.424B, S32.425B, S32.431B, S32.432B, S32.434B, S32.435B, S32.441B, S32.442B, S32.444B, S32.445B, S32.451B, S32.452B, S32.454B, S32.455B, S32.461B, S32.462B, S32.464B, S32.465B, S32.471B, S32.472B, S32.474B, S32.475B, S32.481B, S32.482B, S32.484B, S32.485B, S32.491B, S32.492B, S32.511B, S32.512B, S32.591B, S32.592B, S32.611B, S32.612B, S32.614B, S32.615B, S32.691B, S32.692B, S32.810B, S32.811B, S32.82XB, S32.89XB, S42.291B, S42.292B, S42.294B, S42.295B, S42.321B, S42.322B,

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Vaccination (Immunization) (continued)	Apr. 13, 2022	S42.324B, S42.325B, S42.331B, S42.332B, S42.334B, S42.335B, S42.341B, S42.342B, S42.344B, S42.345B, S42.351B, S42.352B, S42.354B, S42.355B, S42.361B, S42.362B, S42.364B, S42.365B, S42.391B, S42.392B, S42.411B, S42.412B, S42.414B, S42.415B, S42.421B, S42.422B, S42.424B, S42.425B, S42.431B, S42.432B, S42.434B, S42.435B, S42.441B, S42.442B, S42.444B, S42.445B, S42.447B, S42.448B, S42.451B, S42.452B, S42.454B, S42.455B, S42.461B, S42.462B, S42.464B, S42.465B, S42.471B, S42.472B, S42.474B, S42.475B, S42.491B, S42.492B, S42.494B, S42.495B, S52.021B, S52.021C, S52.022B, S52.022C, S52.024B, S52.024C, S52.025B, S52.025C, S52.031B, S52.031C, S52.032B, S52.032C, S52.034B, S52.034C, S52.035B, S52.035C, S52.041B, S52.041C, S52.042B, S52.042C, S52.044B, S52.044C, S52.045B, S52.045C, S52.091B, S52.091C, S52.092B, S52.092C, S52.121B, S52.121C, S52.122B, S52.122C, S52.124B, S52.124C, S52.125B, S52.125C, S52.131B, S52.131C, S52.132B, S52.132C, S52.134B, S52.134C, S52.135B, S52.135C, S52.181B, S52.181C, S52.182B, S52.182C, S52.221B, S52.221C, S52.222B, S52.222C, S52.224B, S52.224C, S52.225B, S52.225C, S52.231B, S52.231C, S52.232B, S52.232C, S52.234B, S52.234C, S52.235B, S52.235C, S52.241B, S52.241C, S52.242B, S52.242C, S52.244B, S52.244C, S52.245B, S52.245C, S52.251B, S52.251C, S52.252B, S52.252C, S52.254B, S52.254C, S52.255B, S52.255C, S52.261B, S52.261C, S52.262B, S52.262C, S52.264B, S52.264C, S52.265B, S52.265C, S52.271B, S52.271C, S52.272B, S52.272C, S52.281B, S52.281C, S52.282B, S52.282C, S52.291B, S52.291C, S52.292B, S52.292C, S52.321B, S52.321C, S52.322B, S52.322C, S52.324B, S52.324C, S52.325B, S52.325C, S52.331B, S52.331C, S52.332B, S52.332C, S52.334B, S52.334C, S52.335B, S52.335C, S52.341B, S52.341C, S52.342B, S52.342C, S52.344B, S52.344C, S52.345B, S52.345C, S52.351B, S52.351C, S52.352B, S52.352C, S52.354B, S52.354C, S52.355B, S52.355C, S52.361B, S52.361C, S52.362B, S52.362C, S52.364B, S52.364C, S52.365B, S52.365C, S52.371B, S52.371C, S52.372B, S52.372C, S52.381B, S52.381C, S52.382B, S52.382C, S52.391B, S52.391C, S52.392B, S52.392C, S52.511B, S52.511C, S52.512B, S52.512C, S52.514B, S52.514C, S52.515B, S52.515C, S52.531B, S52.531C, S52.532B, S52.532C, S52.541B, S52.541C, S52.542B, S52.542C, S52.551B, S52.551C, S52.552B, S52.552C, S52.561B, S52.561C, S52.562B, S52.562C, S52.571B, S52.571C, S52.572B, S52.572C, S52.591B, S52.591C, S52.592B, S52.592C, S52.611B, S52.611C, S52.612B, S52.612C, S52.614B, S52.614C, S52.615B, S52.615C, S52.691B, S52.691C, S52.692B, S52.692C, S72.8X1B, S72.8X1C, S72.8X2B, S72.8X2C, S82.191B, S82.191C, S82.192B, S82.192C, S82.221B, S82.221C, S82.222B, S82.222C, S82.224B, S82.224C, S82.225B, S82.225C, S82.231B, S82.231C, S82.232B, S82.232C, S82.234B, S82.234C, S82.235B, S82.235C, S82.241B, S82.241C, S82.242B, S82.242C, S82.244B, S82.244C, S82.245B, S82.245C, S82.251B, S82.251C, S82.252B, S82.252C, S82.254B, S82.254C, S82.255B, S82.255C, S82.261B, S82.261C, S82.262B, S82.262C, S82.264B, S82.264C, S82.265B, S82.265C, S82.291B, S82.291C, S82.292B, S82.292C, S82.391B, S82.391C, S82.392B, S82.392C, S82.421B, S82.421C, S82.422B, S82.422C, S82.424B, S82.424C, S82.425B, S82.425C, S82.431B, S82.431C, S82.432B, S82.432C, S82.434B, S82.434C, S82.435B, S82.435C, S82.441B, S82.441C, S82.442B, S82.442C, S82.444B, S82.444C, S82.445B, S82.445C,

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Vaccination (Immunization) (continued)	Apr. 13, 2022	S82.451B, S82.451C, S82.452B, S82.452C, S82.454B, S82.454C, S82.455B, S82.455C, S82.461B, S82.461C, S82.462B, S82.462C, S82.464B, S82.464C, S82.465B, S82.465C, S82.491B, S82.491C, S82.492B, S82.492C, S82.51XB, S82.51XC, S82.52XB, S82.52XC, S82.54XB, S82.54XC, S82.55XB, S82.55XC, S82.61XB, S82.61XC, S82.62XB, S82.62XC, S82.64XB, S82.64XC, S82.65XB, S82.65XC, S82.831B, S82.831C, S82.832B, S82.832C, S82.841B, S82.841C, S82.842B, S82.842C, S82.844B, S82.844C, S82.845B, S82.845C, S82.851B, S82.851C, S82.852B, S82.852C, S82.854B, S82.854C, S82.855B, S82.855C, S82.861B, S82.861C, S82.862B, S82.862C, S82.864B, S82.864C, S82.865B, S82.865C, S82.871B, S82.871C, S82.872B, S82.872C, S82.874B, S82.874C, S82.875B, S82.875C, S82.891B, S82.891C, S82.892B, S82.892C, S92.031B, S92.032B, S92.034B, S92.035B, S92.041B, S92.042B, S92.044B, S92.045B, S92.051B, S92.052B, S92.054B, S92.055B, S92.061B, S92.062B, S92.064B, S92.065B, T24.331D, and T24.331S **Supporting Information** • Updated *References* section to reflect the most current information
Vitamin D Testing	Apr. 13, 2022	**Applicable Codes** ***Diagnosis Codes*** **For CPT Code 82306** • Removed K74.0 and N18.3 **For CPT Code 82652** • Removed K74.0 and N18.3 **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Approval Date	Summary of Changes

Enteral and Parenteral Nutritional Therapy (Formerly NCD 180.2)	Apr. 13, 2022	**Title Change**
		• Previously titled *Enteral and Parenteral Nutritional Therapy (NCD 180.2)*
		Policy Summary
		Overview
		• Revised language to indicate:
		  ○ Enteral nutrition is an option for some patients who are unable to meet their nutritional requirements orally but have a functional gut and are able to digest/absorb formula introduced into the lumen of the gastrointestinal (GI) tract
		  ○ Parenteral nutrition is the provision of nutritional requirements intravenously

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Enteral and Parenteral Nutritional Therapy (Formerly NCD 180.2) (continued)	Apr. 13, 2022	*Guidelines*
		• Revised language to indicate:
		  ○ Coverage of enteral and parenteral nutrition under the prosthetic device benefit, as outlined in the *Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120*, requires that a beneficiary must have a permanent impairment; however, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future
		  ○ If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met
		  ○ If the coverage requirements for enteral and parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered
		Enteral Nutrition Therapy
		• Revised language to indicate:
		  ○ Enteral nutrition is covered for a beneficiary who requires feedings via an enteral access device to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status and has a permanent:
		  ▪ Full or partial non-function or disease of the structures that normally permit food to reach the small bowel; or
		  ▪ Disease that impairs digestion and/or absorption of an oral diet, directly or indirectly, by the small bowel
		  ○ Adequate nutrition must not be possible by dietary adjustment and/or oral supplements
		  ○ Typical examples of conditions associated with non-function or disease of the structures that permit food from reaching the small bowel that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding (not all inclusive)
		  ○ Typical examples of conditions associated with impaired digestion and/or absorption of an oral diet by the small bowel that may qualify for coverage include inflammatory bowel disease, surgical resection of small bowel, cystic fibrosis, chronic pancreatitis, and advanced liver disease (not all inclusive)
		  ○ Enteral nutrition for temporary impairments will be denied as non-covered, no benefit
		  ○ Enteral nutrition for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is not due to reasons related to the non-function or disease of the structures that normally permit food to reach the small bowel will be denied as non-covered, no benefit
		  ○ Orally administered enteral nutrition products, related supplies and equipment will be denied non-covered, no benefit
		Parenteral Nutrition Therapy
		• Removed language indicating:

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Enteral and Parenteral Nutritional Therapy (Formerly NCD 180.2) (continued)	Apr. 13, 2022	○ Parenteral nutrition therapy daily is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition ▪ Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day; the catheter is then plugged by the patient until the next infusion ▪ Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training; however, such persons cannot be paid for their services, nor is payment available for any services furnished by non-physician professionals except as services furnished incident to a physician's service ○ For parenteral nutrition therapy to be covered, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met, and that parenteral nutrition therapy is medically necessary ▪ An example of a condition that typically qualifies for coverage is a massive, small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake; if the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump ▪ Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation *Parenteral Nutrition Nutrients* ● Added language to indicate: ○ No more than one month's supply of parenteral nutrients, equipment or supplies is allowed for one month's prospective billing ○ Claims submitted retroactively, however, may include multiple months ● Removed language indicating: ○ Nutrient solutions for parenteral therapy are routinely covered; however, Medicare pays for no more than one month's supply of nutrients at any one time ○ Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so ○ Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter

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Enteral and Parenteral Nutritional Therapy (Formerly NCD 180.2) (continued)	Apr. 13, 2022	circumstances Applicable Codes • Removed HCPCS code A5200 Supporting Information • Updated *References* section to reflect the most current information
Home Use of Oxygen (NCD 240.2)	Apr. 13, 2022	Policy Summary *Overview* • Revised language to indicate oxygen and oxygen equipment, when used in the home, can make meaningful contributions to the treatment of patients with both acute and chronic conditions who require the medical gas on either a short- or long-term basis *Guidelines* • Revised language [in accordance with the Centers for Medicare & Medicaid (CMS) National Coverage Determination (NCD) for Home Use of Oxygen (NCD 240.2)] to indicate: Nationally Covered Indications (new to policy) ○ Effective Sep. 27, 2021, oxygen therapy and oxygen equipment is covered in the home for acute or chronic conditions, short- or long- term, when the patient exhibits hypoxemia as defined [in the policy] ○ Initial claims for oxygen therapy for hypoxemic patients must be based on the results of a clinical test that has been ordered and evaluated by the treating practitioner; such a test is usually in the form of a measurement of the partial pressure of oxygen (PO2) in arterial blood ○ A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the treating practitioner and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services ○ A durable medical equipment (DME) supplier is not considered a qualified provider or supplier of laboratory services for purposes of this NCD ○ This prohibition does not extend to the results of blood gas tests conducted by a hospital certified to do such tests ○ When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need ○ Required qualifying arterial blood gas or oximetry studies must be performed at the time of need; the time of need is defined as during the patient's illness when the presumption is that the provision of oxygen in the home setting will improve the patient's condition ○ For an inpatient hospital patient, the time of need is within 2 days of discharge

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Home Use of Oxygen (NCD 240.2) (continued)	Apr. 13, 2022	○ For those patients whose initial oxygen prescription does not originate during an inpatient hospital stay, the time of need is during the period when the treating practitioner notes signs and symptoms of illness that can be relieved by oxygen in the patient who is to be treated at home ○ Patients exhibiting hypoxemia are defined using the clinical criteria below: *Group I* ▪ An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air; or ▪ An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia); in either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered; portable oxygen, therefore, would not be covered in this situation; or ▪ An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise [defined as either the functional performance of the patient or a formal exercise test], for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest; in this case, supplemental oxygen is provided for during exercise if the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air *Group II* ▪ Coverage is available for patients whose arterial PO2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is: – Dependent edema suggesting congestive heart failure; or, – Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVFL; or, – Erythrocythemia with a hematocrit greater than 56% ○ In reviewing the arterial PO2 levels and the arterial oxygen saturation percentages specified above, the Medicare Administrative Contractors (MACs) must take into account variations in oxygen measurements that may result from such factors as the patient's age, the patient's skin pigmentation, the altitude level, or the patient's decreased oxygen carrying capacity Nationally Non-Covered Indications (new to policy) ○ Effective Sep. 27, 2021, CMS will not cover oxygen therapy and oxygen equipment in the home in the following

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Home Use of Oxygen (NCD 240.2) (continued)	Apr. 13, 2022	circumstances: ▪ Angina pectoris in the absence of hypoxemia; this condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments; or ▪ Breathlessness without cor pulmonale or evidence of hypoxemia; although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting; or ▪ Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities; there is no evidence that increased PO2 improves the oxygenation of tissues with impaired circulation; or ▪ Terminal illnesses unless they affect the ability to breathe Other (new to policy) ○ Effective Sep. 27, 2021, the MAC may determine reasonable and necessary coverage of oxygen therapy and oxygen equipment in the home for patients who are not described in this NCD ○ Initial coverage for patients with other conditions may be limited to the shorter of 120 days or the number of days included in the practitioner prescription at MAC discretion ○ Oxygen coverage may be renewed if deemed medically necessary by the MAC ○ MACs may also allow beneficiaries who are mobile in the home and would benefit from the use of a portable oxygen system in the home to qualify for coverage of a portable oxygen system either (1) by itself, or (2) to use in addition to a stationary oxygen system Supporting Information ● Updated *References* section to reflect the most current information
Mobility Devices (Non-Ambulatory) and Accessories	Apr. 13, 2022	Related Policies ● Added reference link to the Medicare Advantage Coverage Summary titled *Mobility Assistive Equipment (MAE)* Policy Summary *Power Operated Vehicle* Non-Medical Necessity Coverage and Payment Rules ● Added language to indicate: ○ The Centers for Medicare & Medicaid Services (CMS) finds that the evidence is sufficient to determine that the Standard Function of the INDEPENDENCE iBOT 4000 Mobility System meets the definition of Durable Medical Equipment (DME) under *Section 1861(n) of the Social Security Act (the Act)* as a wheelchair used in the patient's home that is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADL), such as feeding, dressing, grooming, toileting, and bathing in customary locations in the home ○ CMS has reviewed the evidence and concludes that the 4-Wheel, Balance, Stair and Remote Functions of the

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Mobility Devices (Non-Ambulatory) and Accessories (continued)	Apr. 13, 2022	INDEPENDENCE iBOT 4000 Mobility System do not meet the definition of DME under *Section 1861(n) of the Act* ● Removed language indicating: ○ For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body beneficiary, and 3) meet all other applicable Medicare statutory and regulatory requirements ○ Information provided in this policy article relates to determinations other than those based on *Social Security Act §1862(a)(1)(A)* provisions (i.e., "reasonable and necessary") *Power Wheelchair* Power Seating Systems ● Updated list of applicable HCPCS codes for a power leg elevation feature; added E1012 with corresponding notation to indicate the unit of service for this code is "each" Questions and Answers (Q&A) ● Replaced reference to "DME 2021 HCPCS Level II book" with "DME *2022* HCPCS Level II book" Supporting Information ● Updated *References* section to reflect the most current information
Molecular Diagnostic Infectious Disease Testing	Apr. 13, 2022	Related Policies ● Added reference link to the Medicare Advantage Reimbursement Policy titled *Molecular Pathology Policy, Professional and Facility* Policy Summary *Overview* ● Revised language to indicate: ○ Molecular panel tests for infectious diseases have changed the landscape of clinical microbiology ▪ They play an important role in diagnostic testing, as they simultaneously detect several different pathogens associated with similar and overlapping clinical symptomatology ▪ For this reason, they are also known as 'syndromic panel' tests; these panels belong to a category of testing known as culture-independent diagnostic tests (CIDTs), which are tests that detect pathogens without the need to grow and isolate them in culture ▪ These tests have shorter turnaround times, often have good test performance characteristics, and require limited technical expertise, making them appealing for use by clinicians as well as clinical laboratories ○ Historically, physicians were required to select the specific pathogens most likely thought to be associated with a patient's disease; they often had to rely on empiric therapy until results from the laboratory could be used in identifying definitive or targeted antimicrobial therapy, with results taking days and sometimes weeks

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Molecular Diagnostic Infectious Disease Testing (continued)	Apr. 13, 2022	▪ In recent years, molecular panel tests, including multiplex PCR, have become increasingly used for the detection of pathogens, and clinicians are no longer required to name (or separately test for) many of the bacterial, viral, fungal, and parasitic species sought for a given clinical 'syndrome' ▪ As the use of multiplex molecular tests have decreased the need to perform multiple assays to diagnose a given infection, results are often available to the physician within minutes to hours ▪ Though culture-based methods of diagnosis are still routinely utilized, and definitive antimicrobial therapy may still lag pending full culture and susceptibility information, these tests have revolutionized infectious disease diagnostics and have made the road from diagnosis to treatment very rapid, in some cases occurring at the point-of-care (POC) *Guidelines* Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (removed) ● Removed content/language pertaining to multiplex nucleic acid amplified tests for respiratory viral panels Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) (removed) ● Removed content/language pertaining to gastrointestinal pathogen (GIP) panels utilizing multiplex nucleic acid amplification techniques (NAATs) Molecular Infectious Disease Panels for Infectious Disease Pathogen Identification Testing (new to policy) ● Added language to indicate: ○ Medicare provides limited coverage for outpatient testing with molecular syndromic panels for infectious disease pathogen identification testing ○ Medicare differentiates (where appropriate) between small, targeted panels (up to 5 pathogens) and larger, expanded panels (≥ 6 pathogens); this distinction is primarily applied to the respiratory and gastrointestinal panels ○ Examples of molecular infectious disease panels addressed by Medicare include but are not limited to: ▪ Targeted respiratory panels (3-5 targets) ▪ Expanded respiratory and pneumonia panels (> 5 targets) ▪ Targeted gastrointestinal panels (3-5 targets) ▪ Expanded gastrointestinal panels (> 5 targets) ▪ Meningoencephalitis panels ▪ Bloodstream infection panels ▪ Urogenital/anogenital panels *Nationally Non-Covered Indications (new to policy)* ● Added language to indicate:

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Molecular Diagnostic Infectious Disease Testing (continued)	Apr. 13, 2022	○ Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review ○ *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)* states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." ○ It has been longstanding CMS policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute" ○ For certain panels, such as the urogenital/anogenital panel, epidemiologic indication or potential exposure to pathogens as a result of a high-risk experience is considered a covered clinical indication, even in the absence of clinical symptoms Applicable Codes *CPT Codes* Non-Covered ● Relocated/reclassified 0115U, 0202U, 0223U, 0225U, 87632, 87633 (refer to list of *Provisional* codes) ● Added notation to indicate 0151U was “deleted Mar. 31, 2022” Provisional Coverage ● Added 0115U, 0202U, 0223U, 0225U, 81513, 81514, 87154, 87483, 87625, 87632, and 87633 ● Removed 87490, 87491, 87534, 87535, 87536, 87537, 87538, 87539, 87590, and 87591 ● Added notation to indicate 0097U was “deleted Mar. 31, 2022” *Diagnosis Codes* For CPT Codes 87631, 87636, 87637, 0240U, and 0241U (Facility Only) ● Added A37.00, A37.01, A37.10, A37.11, A37.80, A37.81, A37.90, A37.91, A41.81, A41.89, A41.9, A48.1, A48.2, B25.0, B33.23, B33.24, B59, B97.21, J10.01, J10.08, J10.1, J10.2, J10.81, J10.82, J10.83, J10.89, J11.08, J11.1, J11.2, J11.81, J11.82, J11.83, J11.89, J12.2, J13, J15.0, J15.1, J15.20, J15.211, J15.212, J15.29, J15.3, J15.4, J15.7, J15.9, J16.0, J20.0, J20.1, J20.2, J20.3, J20.4, J20.5, J20.6, J20.9, J21.9, J45.901, J45.902, J85.0, J85.1, J85.2, J85.3, R65.20, R65.21, R78.81, T86.33, and T86.812 ● Added notation to indicate D80.7, D80.9, D81.30, D81.819, D81.9, D82.9, D83.9, T80.82XS, Z86.16, Z92.850, Z92.858, Z92.86, Z94.0, Z94.1, Z94.2, Z94.3, Z94.4, Z94.5, Z94.6, Z94.81, Z94.82, Z94.83, and Z94.84 were “deleted Apr. 17, 2022” For CPT Codes 87505 and 87506 (Facility Only) ● Added A02.1, A08.19, A08.31, A08.39, A08.8, A41.50, A41.51, A41.52, A41.53, A41.59, A41.81, A41.89, A41.9, K50.014, K50.114, K50.814, K50.914, K51.014, K51.214, K51.314, K51.414, K51.514, K51.814, K51.914, K52.1, K92.1, R10.11, R10.12, R10.13, R10.31, R10.32, R10.33, R10.811, R10.812, R10.813, R10.814, R10.815, R10.817, R10.821,

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Molecular Diagnostic Infectious Disease Testing (continued)	Apr. 13, 2022	R10.822, R10.823, R10.824, R10.825, R10.826, R10.827, R10.829, R10.84, R19.5, R50.9, R65.20, R65.21, R78.81, and T86.852 For CPT Codes 0097U, 87506, and 87507 (Facility Only) • Added B25.1, B25.2, C46.0, C46.1, C46.2, C46.3, C46.4, C46.50, C46.51, C46.52, C46.7, E08.43, E10.43, E11.43, E13.43, K50.011, K50.012, K50.013, K50.018, K50.111, K50.112, K50.113, K50.118, K50.812, K50.813, K50.818, K50.911, K50.912, K50.913, K50.918, K51.011, K51.012, K51.013, K51.018, K51.019, K51.211, K51.212, K51.213, K51.218, K51.219, K51.311, K51.312, K51.313, K51.318, K51.319, K51.411, K51.412, K51.413, K51.418, K51.419, K51.511, K51.512, K51.513, K51.518, K51.519, K51.811, K51.812, K51.813, K51.818, K51.911, K51.912, K51.913, K51.918, K52.0, K56.3, K62.7, O98.711, O98.712, O98.713, Z51.11, and Z94.89 • Added notation to indicate A41.9, R65.20, and R65.21 were "deleted Apr. 17, 2022" *Coding Clarification* • Added notation to indicate ICD-10 diagnosis code Z04.81 is excluded from Non-Coverage for CPT codes 81513, 81514, 87623, 87624, 87625, 87800, and 87801 Definitions • Added definition of: ○ Panel ○ Syndromic Panel Questions and Answers (Q&A) • Updated Q&A pertaining to coverage of respiratory viral panel codes • Removed Q&A pertaining to non-covered respiratory viral panels Supporting Information • Updated *References* section to reflect the most current information
Molecular Pathology/Genetic Testing Reported with Unlisted Codes	Apr. 13, 2022	Policy Summary *Guidelines* • Added language to indicate: ○ For laboratory services, a service can be reasonable and necessary if the service is safe and effective; *not experimental or investigational (exception: routine costs of qualifying clinical trial services which meet the requirements of the Clinical Trials National Coverage Determination (NCD) and are considered reasonable and necessary)*; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition *or to improve the function of a malformed body member* *Nationally Non-Covered Indications*

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Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	• Revised language pertaining to screening services to indicate:
		  ○ Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and not covered
		  ○ Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient
		Utilization Guidelines (removed)
		• Removed content/language addressing non-covered screening services (duplicative to language outlined in the section titled *Nationally Non-Covered Indications*)
		Covered Indications
		For CPT Code 81479
		Guardant360®
		• Updated list of conditions for/in which Guardant360® is covered:
		  ○ Replaced:
		  ▪ "Patient has not previously been tested with the Guardant360® test for the same *primary cancer*, for patient who has been tested previously using Guardant360® for cancer, that patient may not be tested again unless *he or she has a new primary cancer diagnosis*" with "patient has not previously been tested with the Guardant360® test for the same *genetic content*; for a patient who has been tested previously using Guardant360® for cancer, that patient may not be tested again unless *there is clinical evidence that the cancer has evolved wherein testing would be performed for different genetic content*"
		  ▪ "Patient is untreated for the *primary* cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment)" with "patient is untreated for the cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment)"
		HERmark® Assay (removed)
		• Removed content/language pertaining to the HERmark® test
		InVisionFirst, Liquid Biopsy
		• Updated list of indications for limited coverage of InVisionFirst for patients with advanced (Stage IIIB/IV) non-small cell lung cancer (NSCLC); replaced "at diagnosis *and untreated* [when listed criteria are met]" with "at diagnosis [when listed criteria are met]"
		• Added language to indicate tissue-based genotyping should be considered if no genetic alteration is detected by InVision® or if circulating tumor DNA (ctDNA) is insufficient/not detected
		MammaPrint®
		• Updated description of "MammaPrint®"

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Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	• Added language to indicate:
		  ○ The test can be performed using either a FDA-cleared in vitro microarray assay or a next generation sequencing (NGS)-based assay
		  ○ Only one test-NGS or microarray may be performed on a given date of service for a given patient
		Next-Generation Sequencing for Solid Tumors and for Myeloid Malignancies and Suspected Myeloid Malignancies (new to policy)
		• Added language to indicate:
		  ○ Next-Generation Sequencing (NGS) is not a specific test, but a sequencing methodology utilized to capture genomic information
		  ▪ Unlike Sanger sequencing (the prior standard technology) that typically provides sequence information for a single deoxyribonucleic acid (DNA) strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently; this allows for capturing many relevant genomic targets simultaneously, usually by utilizing capture technologies such as by polymerase chain reaction (PCR) amplification or hybrid capture
		  ▪ NGS tests for use in cancer are often comprised of gene panels whose content is either relevant to a specific tumor type or condition, or a larger panel of genes that can be used for multiple tumor types
		  ○ For Next-Generation Sequencing for solid tumors:
		  ▪ All the following must be present for coverage eligibility:
		  – As per National Coverage Determination (NCD 90.2), this test is reasonable and necessary when the patient has either:
		  • Recurrent cancer, relapsed cancer, refractory cancer, metastatic cancer, advanced cancer (stages III or IV); and
		  • Has not been previously tested by the same test for the same genetic content; and
		  • Is seeking further treatment
		  – The test has satisfactorily completed a Technical Assessment (TA) for the stated indications of the test
		  – The assay performed includes at least the minimum genes and genomic positions required for the identification of clinically relevant FDA-approved therapies with a companion diagnostic biomarker as well as other biomarkers known to be necessary for clinical decision making for its intended use that can be reasonably detected by the test; these genes and variants will change as the literature and drug indications evolve
		  ▪ The test in question will be non-covered if:
		  – It does not fulfill all the criteria set forth in the NCD 90.2 as stated above
		  – Another CGP test was performed on the same tumor specimen (specimen obtained on the same date of

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Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	service) – A TA is not completed satisfactorily for new tests ○ For Next-Generation Sequencing for myeloid malignancies and suspected myeloid malignancies: ▪ The following must be present for coverage eligibility: – For tests that are specifically indicated in patients who are known to have a myeloid malignancy at the time of testing, NCD 90.2 applies – The patient has a diagnosis of AML, MDS, or MPN. AML, MDS, and MPN are herein classified as refractory and/or metastatic cancers and fulfil the NCD 90.2 criteria – The test has satisfactorily completed a TA for the stated indications of the test – The assay performed includes at least the minimum genes and positions indicated for its intended use – For patients that do not have a diagnosis of a myeloid malignancy, where one is suspected, the patient must have an undefined cytopenia for greater than 4 months, other possible causes have been reasonably excluded – Testing is performed on bone marrow biopsies, bone marrow aspirates, bone marrow clots, peripheral blood samples, or extramedullary sites suspected of harboring a myeloid malignancy ▪ The test in question will be non-covered if: – A TA has not been satisfactorily completed – Another NGS test was performed on the same surgical specimen/blood draw (specimen obtained on the same date of service) – Testing falls within scope of NCD 90.2 and has been tested with the same test for the same genetic content *Pharmacogenomics Testing (PGx)* • Modified content heading; previously titled *Pharmacogenomics Testing* • Added language to indicate: ○ The selection of the medications in question must be derived from clinical factors/necessity rather than from a PGx test; once the putative therapeutic agents are selected, and those agents are known to have gene-drug interactions as identified [in the policy], then a PGx test may be considered reasonable and necessary when the result of that test is necessary for the physician's decision-making process regarding safely administering or dosing the drug ○ PGx testing is not covered when a treating clinician is not considering treatment with a medication that has an actionable drug-gene interaction, or when the use of a medication with a drug-gene interaction is not reasonable and necessary ○ If a treating clinician orders a single gene test or a test for a particular allele(s), but as a matter of operational

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Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	practicality, the laboratory tests that single gene or allele on a platform that looks for variants in other genes/alleles as well, that particular test done in that particular instance is considered a single gene/allele test for coverage purposes; in this scenario the provider may bill for the component of the test that was reasonable and necessary (in this example, the single gene test) ○ Minimum criteria are determined by experts including relevant associations such as the Association for Molecular Pathology and are considered during the technical assessment; a multi-gene panel is not considered reasonable and necessary if only a single gene on the panel is considered reasonable and necessary • Updated list of genes/genetic tests requiring submission with CPT code 81479 (no specific CPT code available); removed CYP2C8 *Phenotypic Biomarker Detection from Circulating Tumor Cells* • Revised coverage criteria for assays that detect biomarkers from circulating tumor cells (CTCs); replaced criterion requiring "the CTC-based biomarker test successfully completes a comprehensive TA *by MolDX* that will ensure that Analytical Validity (AV) (including an analytical and clinical validation), Clinical Validity (CV), and CU criteria are met to establish the test as reasonable and necessary" with "the CTC-based biomarker test successfully completes a comprehensive TA that will ensure that Analytical Validity (AV) (including an analytical and clinical validation), Clinical Validity (CV), and CU criteria are met to establish the test as reasonable and necessary" *Prognostic and Predictive Molecular Classifiers for Bladder Cancer* • Revised language to indicate molecular diagnostic tests for use in a beneficiary with bladder cancer are covered when all of the following conditions are met: ○ The beneficiary is being actively managed for bladder cancer ○ The beneficiary is within the population and has the indication for which the test was developed and is covered; the lab providing the test is responsible for clearly indicating to treating clinicians the population and indication for test use ○ At least 1 of the 2 criteria are met: ▪ The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments; or ▪ The patient is a candidate for multiple therapies, and the test has shown that it predicts response to a specific therapy among accepted therapy options based on nationally recognized consensus guidelines ○ The test demonstrates analytical validity including both analytical and clinical validations; if the test relies on an algorithm (which may range in complexity from a threshold determination of a single numeric value to a complex mathematical or computational function), the algorithm must be validated in a cohort that is not a development cohort for the algorithm

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Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	○ The test has demonstrated clinical validity and utility, establishing a clear and significant biological/molecular basis for stratifying patients and subsequently selecting (either positively or negatively) a clinical management decision *(in the 4th bullet above)* in a clearly defined population ○ The test successfully completes a technical assessment that ensures the test is reasonable and necessary *(as described in the 4th and 5th bullets above)* *Solid Organ Allograft Rejection* ● Updated list of reasonable and necessary molecular diagnostic tests; added: ○ AlloMap® (Care Dx®) ○ Viracor TRAC™ (Transplant Rejection Allograft Check) (Eurofins) ○ QSant *Targeted and Comprehensive Genomic Profile Next Generation Sequencing (NGS) Testing* ● Replaced language indicating: ○ "Comprehensive genomic profile (CGP) is not defined as a targeted panel *by MolDX*" with "comprehensive genomic profile (CGP) is not defined as a targeted panel" ○ "A targeted NGS panel which includes *1 to 4* genes *would be appropriately reported* with CPT code 81479" with "*laboratories* with *2 to 4* genes on their targeted NGS panel *should use* CPT code 81479" Applicable Codes *Molecular Pathology/Genetic Testing Reported with Unlisted Codes: Diagnosis Codes* For CPT Code 81479 (Biomarker JAK1) ● Added C95.91 and C95.92 For CPT Code 81479 (ClonoSEQ® Assay) ● Added Z85.6 and Z85.79 For CPT Code 81479 (Prognostic and Predictive Molecular Classifiers for Bladder Cancer) ● Modified content heading; previously listed as *For CPT Code 81479 Decipher Bladder, FGFR2, FGFR3* For CPT Code 81479 (Genesight, NeuroIDgenetix, Genomind Professional PGx Express™ or Neuropharmagen) ● Added notation to indicate F32.9, F33.40, and F33.9 were "deleted Jan. 1, 2021" For CPT Code 81479 (Minimal Residual Disease Testing for Solid Tumor Cancers) ● Modified content heading; previously listed as *For CPT code 81479 Minimal Residual Disease Testing for Cancer* ● Added C46.0, C46.1, C46.2, C46.3, C46.4, C46.50, C46.51, C46.52, C46.7, and C46.9 For CPT Code 81479 (Androgen Receptor Variant AR-V7 Protein Test) ● Added notation to indicate C78.00 and C78.30 were "deleted Nov. 8, 2021"

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Policy Title	**Approval Date**	**Summary of Changes**
Molecular Pathology/Genetic Testing Reported with Unlisted Codes (continued)	Apr. 13, 2022	For CPT Code 81479 (Pharmacogenomics Testing CYP2B6) • Removed/relocated I21.9, I22.9, I23.6, I25.2, I26.02, I26.09, I26.92, I26.93, I26.94, I26.99, I48.11, I48.19, I48.20, I48.21, I51.3, I82.890, I82.891, T82.817A, T82.817D, T82.817S, T82.818A, T82.818D, T82.818S, T82.867A, T82.867D, T82.867S, T82.868A, T82.868D, T82.868S, Z79.01, Z79.02, Z86.711, Z86.718, Z86.79, Z95.2, and Z95.4 (refer to list of *Pharmacogenomics Testing CYP4F2* codes) For CPT Code 81479 (Pharmacogenomics Testing CYP4F2) • Added I21.9, I22.9, I23.6, I25.2, I26.02, I26.09, I26.92, I26.93, I26.94, I26.99, I48.11, I48.19, I48.20, I48.21, I51.3, I82.890, I82.891, T82.817A, T82.817D, T82.817S, T82.818A, T82.818D, T82.818S, T82.867A, T82.867D, T82.867S, T82.868A, T82.868D, T82.868S, Z79.01, Z79.02, Z86.711, Z86.718, Z86.79, Z95.2, and Z95.4 For CPT Code 81479 (Targeted and Comprehensive Genomic Profile Next Generation Sequencing (NGS) Testing for Myeloid Malignancies) • Added C92.90, C92.91, C92.92, C93.90, C93.92, D61.9, D64.9, and D69.6 • Removed notation indicating D46.4 and D46.9 were "deleted Jun. 30, 2021" For CPT Code 81479 (Targeted and Comprehensive Genomic Profile Next Generation Sequencing (NGS) Testing for Solid Tumors) • Removed notation indicating C67.9, C68.9, C69.91, C69.92, C70.9, C71.9, C72.20, C72.30, C72.40, C72.50, C72.9, C74.00, C74.10, C74.90, C74.91, C74.92, C75.8, C75.9, C76.40, C76.50, C7A.00, C7A.019, C7A.029, C7A.094, C7A.095, C7A.096, C80.0, and C80.1 were "deleted Jun. 25, 2021" For CPT Code 81599 (DecisionDx-Melanoma Risk Stratification Molecular Testing Classifier) • Modified content heading; previously listed as *For CPT Code 81599 DecisionDx-Melanoma* Supporting Information • Updated *References* section to reflect the most current information
Qualitative Drug Testing for Indications Other Than Mental Health	Apr. 13, 2022	Policy Summary *Overview* • Replaced language indicating: ○ "Urine is the best specimen for broad *qualitative* screening, as blood is relatively insensitive for many common drugs, including stimulants, opioids, and psychotropic agents" with "urine is the best specimen for broad *presumptive* screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants" ○ "Methods of drug analysis include immunoassay, spectrometry, chromatography, and chemical ("spot") tests" with "*common* methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and

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Policy Title	Approval Date	Summary of Changes
Qualitative Drug Testing for Indications Other than Mental Health (continued)	Apr. 13, 2022	spectrometry" ○ "Drugs or classes of drugs are commonly assayed by a qualitative/presumptive *screen*" with "drugs or classes of drugs are commonly assayed by a qualitative/presumptive *testing*" ○ A qualitative/presumptive drug screen may be indicated with a symptomatic patient when the history is unreliable, with multiple-drug ingestion, with a patient in delirium or coma, for the identification of specific drugs, *and to* indicate when antagonists may be used" with "a qualitative/presumptive drug screen may be indicated with a symptomatic patient when the history is unreliable, with multiple-drug ingestion, with a patient in delirium or coma, *or* for the identification of specific drugs *that may* indicate when antagonists may be used" *Guidelines* • Replaced language indicating: ○ "Only one presumptive service may be billed per patient, per *encounter*, regardless of the provider" with "only one presumptive service may be billed per patient, per *date of service (DOS)*, regardless of the provider" ○ "*Medicare regards* drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) *as not medically necessary*" with "drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) *are not covered*" Applicable Codes • Added CPT code 0227U Definitions • Updated definition of: ○ Presumptive/Qualitative Drug Testing ○ Definitive/Quantitative/Confirmation Supporting Information • Updated *References* section to reflect the most current information

Retired

The following Policy Guidelines have been retired effective Apr. 13, 2022:

- Gastrophotography (NCD 100.12)
- INDEPENDENCE iBOT 4000 Mobility System (NCD 280.15)
- Multiple Electroconvulsive Therapy (MECT) (NCD 160.25)
- Oxygen Treatment of Inner Ear/Carbon Therapy (NCD 50.5)

General Information

This bulletin provides a list of new, updated, revised, replaced and/or retired UnitedHealthcare Medicare Advantage Policy Guidelines to reflect the most current clinical coverage rules and guidelines developed by the Centers for Medicare & Medicaid Services (CMS). The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medicare Advantage Policy Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New coverage guidelines have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the coverage guidelines; however, items such as the definitions or references may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the coverage guidelines

Replaced

An existing policy has been replaced with a new or different policy

Retired

An existing policy has been retired because national and local coverage determinations from the Centers for Medicare and Medicaid Services (CMS) are no longer available or the applicable coverage guidelines are documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable CMS, federal, or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

The complete library of UnitedHealthcare Medicare Advantage Policy Guidelines is available at UHCprovider.com > Policies and Protocols > Medicare Advantage Policies > Policy Guidelines.