ASCOM Insurance – Reimbursement Updates – May 16, 2019

FDA Hematology/Oncology Approvals & Safety Notifications

https://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm279174.htm

*FDA does not issue approval announcements for every approval or drug label update that occurs in oncology and hematology. Please refer to Drugs@FDA for the latest approvals and prescribing information for specific products.

2019

- FDA approved ramucirumab (CYRAMZA, Eli Lilly and Company) as a single agent for hepatocellular carcinoma (HCC) in patients who have an alpha fetoprotein (AFP) of ≥ 400 ng/mL and have been previously treated with sorafenib. More Information. May 10, 2019
- FDA approved ado-trastuzumab emtansine (KADCYLA, Genentech, Inc.) for the adjuvant treatment of patients with HER2-positive early breast cancer (EBC) who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. More Information. May 3, 2019
- FDA approved ivosidenib (TIBSOVO, Agios Pharmaceuticals, Inc.) for newly-diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy. More Information. May 2, 2019
- FDA approved pembrolizumab (KEYTRUDA, Merck & Co. Inc.) plus axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).More Information, April 19, 2019
- FDA granted accelerated approval to erdafitinib (BALVERSA, Janssen Pharmaceutical Companies) for patients with locally advanced or metastatic urothelial carcinoma, with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. More Information. April 12, 2019
- FDA approved pembrolizumab (KEYTRUDA, Merck Inc.) for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC. Patients' tumors must have no EGFR or ALK genomic aberrations and express PD-L1 (Tumor Proportion Score [TPS] ≥1%) determined by an FDA-approved test. More Information. April 11, 2019
- FDA approved atezolizumab (TECENTRIQ, Genentech Inc.) in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). More Information. March 18, 2019
- FDA approves atezolizumab for PD-L1 positive unresectable locally advanced or metastatic triple-negative breast cancer. More information. March 8, 2019
- FDA approved trastuzumab and hyaluronidase-oysk injection, for subcutaneous use (Herceptin Hylecta, Genentech Inc.). Herceptin Hylecta is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, for the treatment of HER2 overexpressing breast cancer. More Information. February 28, 2019
- FDA approved trifluridine/ tipiracil tablets (LONSURF, Taiho Pharmaceutical Co., Ltd.)—a fixed combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor—for adult patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. More Information. February 22, 2019.
- FDA approved pembrolizumab (KEYTRUDA, Merck) for the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection. More Information. February 15, 2019
- FDA approved caplacizumab-yhdp (CABLIVI, Ablynx NV) for adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. More Information, February 6, 2019.
- FDA approved cabozantinib (CABOMETYX, Exelixis, Inc.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. More Information, January 14, 2019

Medicare

Fee Schedules

Jan and April 2019 Quarterly Drug file updates and NDC/HCPCS crosswalk files -
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html

Jan and April 2019 OPPS fee schedule update Addendum B-
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending

Clinical Lab Fee schedule files are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html

Receive ADRs Electronically:

Go Green via eServices Providers can opt to receive Additional Documentation Requests (ADRs) through eServices. If your claim is selected for review, you can receive your request as it is generated – instead of by mail (which decreases the amount of time you have to respond). This process is free, secure and easy to use. Our messaging function in eServices will send an inbox message to let users know that an 'eLetter' is now available. This new process delivers the electronic document as a link within the secure message once you sign into eServices. For more information about eServices and the many services it offers, please visit our website at www.PalmettoGBA.com/eServices.

Evaluation and Management (E/M) When Performed with Superficial Radiation Treatment

MLN Matters Number: MM11137 Revised Related CR Release Date: February 22, 2019 Related CR Transmittal Number: R4246CP Related Change Request (CR) Number: 11137 Effective Date: January 1, 2019 Implementation Date: March 25, 2019

CR11137 revises Chapter 13 of the Medicare Claims Processing Manual to allow providers to bill E/M codes 99211, 99212, and 99213 for Levels I through III, when performed with superficial radiation treatment delivery (up to 200 kV), when performed for the purpose of reporting physician work associated with: • Radiation therapy planning • Radiation treatment device construction • Radiation treatment management when performed on the same date of service as superficial radiation treatment delivery Make sure your billing staffs are aware of these revisions.

A/B MAC Local Coverage Determination Update References

White Cell Colony Stimulating Factors L37176 Rev #10	Under ***Coverage Indications, Limitations and/or Medical Necessity- II. FDA Indications*** removed italicized text from all verbiage. Under ***Use in Bone Marrow Transplantation Failure or Engraftment Delay*** changed verbiage to read "it is indicated in patients who have undergone allogeneic or autologous bone marrow transplantation (BMT) in which engraftment is delayed or has failed." Under ***Sources of Information*** added U.S. Food and Drug Administration (FDA) sources for Neulasta®, Fulphila™, Granix®, Neupogen®, Zarxio®, and Leukine®. Under ***Bibliography*** removed U.S. Food and Drug Administration (FDA) sources for Granix® and Zarxio®. The resource for Myeloid Growth Factors was corrected to reflect AMA citation guidelines. Formatting, punctuation and typographical errors were corrected throughout the policy and acronyms were inserted where appropriate. This revision is due to the annual validation process. Under ***CPT/HCPCS Codes Group 1: Codes*** added Q5111. Under ***ICD-10 Codes that Support Medical Necessity Group 1, Group 2, Group 3, Group 4, Group 7, and Group 8: Paragraph*** added Q5111. This revision is due to a new HCPCS code assignment for Udenyca™.	1/1/2019

Rituximab (Rituxan®) L35026 Rev #23	Under ***Coverage Indications, Limitations, and/or Medical Necessity Accepted Off-label Uses Approved by Palmetto GBA*** formatting, punctuation and typographical errors were corrected throughout the policy. Acronyms were inserted where appropriate throughout the policy. Under ***Bibliography*** changes were made to citations to reflect AMA citation guidelines.	3/14/2019

Rituximab (Rituxan®) L35026 Rev #24	All coding located in the ***Coding Information*** section has been moved into the related Billing and Coding for Rituximab (Rituxan®) article and removed from the LCD. Under ***Covered ICD-10 Codes Group 2: Codes*** *added ICD-10* codes T86.11, T86.21 and T86.31.	3/14/2019

Billing and Coding: Rituximab (Rituxan®) A56380 Rev #1	**Revision 1:** Under ***Covered ICD-10 Codes Group 2: Codes*** added T86.11, T86.21 and T86.31.	4/8/2019

Billing and Coding for Chemotherapy (A56141)
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56141

Billing and Coding of Drug and Biological Infusions (A55297)
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55297
4/12/19 updated added J3380 Entyvio to the section allowing it be billed with chemo admin code

FUTURE Local Coverage Article:

Billing and Coding: Octreotide Acetate for Injectable Suspension (Sandostatin LAR® depot) (A56531)
https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56531&ver=5&Cntrctr=394&ContrVer=1&CntrctrSelected=394*1&DocType=Active&bc=AAABAAIAgAAA& **5/29/19 diagnosis added**

Medicare Molecular Diagnostic Service coverage updates

Article Title	Article Revision	Effective Date
MolDX: Myriad's BRACAnalysis CDx™ Coding and Billing Guidelines A54338, #11	Added "men" to the first paragraph to include them in treatment for metastatic breast cancer. Also included non-coverage indications.	2/21/2019
MolDX: Myriad's BRACAnalysis CDx™ Coding and Billing Guidelines A54338, #11	Added "men" to the first paragraph to include them in treatment for metastatic breast cancer. Also included non-coverage indications.	2/21/2019

MolDX Local Coverage Determinations

Policy Title	LCD Revision	Effective Date
MolDX: Breast Cancer IndexTM (BCI) Gene Expression Test L37794, #1	Revised the policy to include the CPT/HCPCS and ICD-10 Codes. HCPCS/ CPT Code: 81518 was added to Group 1. C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, Z17.0 was added to the ICD-10 Codes Group 1.	3/11/2019
MolDX: Envisia, Veracyte, Idiopathic Pulmonary Fibrosis Diagnostic Test L37857, Notice	This LCD version was created as a result of DL37857 being released to a Final LCD.	4/1/2019
MolDX: Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Very Low and Low Risk Disease L37785, Notice	This LCD version was created as a result of DL37785 being released to a Final LCD.	4/1/2019
MolDX: DecisionDx-UM (Uveal Melanoma) L37033, #5	Added 0081U to CPT/HCPCS Codes Group 1. Deleted 81599. The change is due to the Q1:2019 CPT/HCPCS Quarterly Update and is effective 1/1/2019. Deleted the Demirci reference in the Clinical Performance Validity Table.	2/21/2019
MolDX: BDX-XL2 L37031, #6	Removed 81599 in CPT/HCPCS Group 1 and added 0080U. This revision is due to the 2019 Q1 CPT/HCPCS Updates and is effective 1/1/2019.	1/1/2019
MolDX: Molecular Diagnostic Tests (MDT) L35025, #24	Either the short and/or long code description was changed for the following codes: 0008U descriptor was changed in Group 1, 0011M descriptor was changed in Group 1. This change is due to the CPT/HCPCS 2019 Q1 update and is effective 1/1/2019.	1/1/2019
MolDX: MDS FISH L37602, Notice	This LCD version was created as a result of DL37602 being released to a Final LCD.	4/8/2019
MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer L37870, Notice	This LCD version was created as a result of DL37870 being released to a Final LCD.	4/8/2019

National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions, 110.21 Last Updated: **01/25/2019**

National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21) (PDF, 535 KB) outlines the national non-covered indications. Subsequently, the Centers for Medicare & Medicaid Services (CMS) has issued several MLN Matters (MM) articles regarding these services.

In MM5818 (PDF, 101 KB), CMS further defines when ESA will be considered non-covered when billed with HCPCS modifier EC, EB, or EA.

MM10318 (PDF, 210 KB), issued in April 2018, made retroactive a list of ICD-10 codes to be considered non-covered for ESA services; however, the editing was turned off (per CMS direction) prior to implementation of this MM article.

In November 2018, CMS issued MM10859 (PDF, 208 KB) that required Medicare Administrative Contractors (MACs) to reactivate edits identified in MM10318, effective January 1, 2019, retroactive to dates of service on or after January 1, 2017. The CMS MM10859 (PDF, 208 KB) includes a link to the current list of the ICD-10 codes that are hardcoded as non-covered for ESAs when submitted with HCPCS modifier EC.

Providers may previously have been reimbursed with one of these non-covered diagnosis codes; however, with the reactivation of the edit, the processing system looks for the modifier and one of the non-covered diagnosis codes anywhere on the claim, claim level or line level, as required by the NCD.
Review the NCD and the referenced MM articles for full details regarding the individual modifier requirements and when the list of non-covered diagnosis codes applies.

Railroad Palmetto GBA targeting E/M services for review below are some of the 2019 error rates and reasons for denials
Denials related to lack of record response
Incomplete documentation or no medical necessity
Physician Signatures not compliant

Initial & Subsequent Hospital Inpatient Care
New Patient visits 99204/ 99205
Critical Care Services

Medicare has a 90 reference guide for E/M services can be found at:
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf

Comparative Billing Reports are available online with Palmetto GBA if you want to see how your providers compare to others in their specialty related to E/M services.
https://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/JM%20Part%20B~eServices%20Portal~eCBR?open&Expand=1

May 2019 UnitedHealthcare Updates - https://www.uhcprovider.com/

Front & Center

Updates to Requirements for Specialty Medical Injectable Drugs for UnitedHealthcare Commercial and Community Plan

We're making some updates to our requirements for certain specialty medications for many of our UnitedHealthcare commercial and Community Plan members. These requirements are important to provide our members access to care that's medically appropriate as we work toward the Triple Aim of improving health care services, health outcomes and overall cost of care. These requirements will apply whether members are new to therapy or have already been receiving these medications.

What's Changing for UnitedHealthcare Community Plan

Spravato™ has been added to the **Review at Launch Drug List** for UnitedHealthcare Community Plan. This list is located at **UHCprovider.com/en/policies-protocols/comm-planmedicaid-policies/medicaid-community-state-policies.html** through the *Review at Launch for New to Market Medications* drug policy.

What's Changing for UnitedHealthcare Commercial and Community Plan Members

Clinical Policy and Prior Authorization Updates

Effective July 1, 2019, our White Blood Cell Colony Stimulating Factors medical drug policy will be updated to include preferred product coverage criteria. Preferred product language will be added as follows:

- Use of Neulasta® Onpro® and Neulasta® vial prior to the use of Fulphila™ and Udenyca™

In addition to the preferred product changes to the drug policy, UnitedHealthcare commercial plans will be expanding the current prior authorization requirements on these medications to include use for any diagnosis:

- Neulasta Onpro/Neulasta, Fulphila, and Udenyca currently require prior authorization when used to treat a cancer diagnosis.
- On July 1, 2019, for UnitedHealthcare commercial plans (including affiliated plans for Oxford, UMR and Neighborhood Health Partnership) use of these medications for all diagnoses will require prior authorization with this policy change.
- On Aug. 1, 2019, for UnitedHealthcare affiliate plans UnitedHealthcare of the Mid-Atlantic and UnitedHealthcare of the River Valley, use of these medications for all diagnoses will require prior authorization.

For both UnitedHealthcare commercial and Community Plan members, current authorizations will be honored through their end date. Upon authorization renewal, the updated policy will apply. Care providers are encouraged to begin using the preferred Colony Stimulating Factor products.

If you administer any of these medications without first completing the notification/prior authorization process, the claim may be denied. Members can't be billed for services denied due to failure to complete the notification/prior authorization process.

UnitedHealthcare Commercial

UnitedHealthcare Medical Policy, Medical Benefit Drug Policy and Coverage Determination Guideline Updates

For complete details on the policy updates listed in the following table, please refer to the **April 2019 Medical Policy Update Bulletin** at **UHCprovider.com > Menu > Policies and Protocols > Commercial Policies > Commercial Medical & Drug Policies and Coverage Determination Guidelines > Medical Policy Update Bulletins**.

Policy Title	Policy Type	Effective Date
NEW		
Preimplantation Genetic Testing	Medical	June 1, 2019
UPDATED/REVISED		
Actemra® (Tocilizumab) Injection for Intravenous Infusion	Drug	April 1, 2019
Bone or Soft Tissue Healing and Fusion Enhancement Products	Medical	April 1, 2019
Breast Reconstruction Post Mastectomy	CDG	May 1, 2019
Breast Repair/Reconstruction Not Following Mastectomy	CDG	May 1, 2019
Chromosome Microarray Testing (Non-Oncology Conditions)	Medical	June 1, 2019
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Drug	April 1, 2019
Cochlear Implants	Medical	April 1, 2019
Computerized Dynamic Posturography	Medical	April 1, 2019
Denosumab (Prolia® & Xgeva®)	Drug	April 1, 2019
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements	CDG	April 1, 2019
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation	Medical	April 1, 2019
Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome	Medical	April 1, 2019
Fecal Calprotectin Testing	Medical	April 7, 2019
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Medical	May 1, 2019

UnitedHealthcare Commercial

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UnitedHealthcare Medical Policy, Medical Benefit Drug Policy and Coverage Determination Guideline Updates

Policy Title	Policy Type	Effective Date
UPDATED/REVISED		
Infliximab (Remicade®, Inflectra™, Renflexis™)	Drug	April 1, 2019
Intrauterine Fetal Surgery	Medical	May 1, 2019
Ketamine	Medical	April 1, 2019
Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan — Site of Care	URG	April 1, 2019
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical	April 1, 2019
Occipital Neuralgia and Headache Treatment	Medical	April 1, 2019
Ocrevus™ (Ocrelizumab)	Drug	April 1, 2019
Orencia® (Abatacept) Injection for Intravenous Infusion	Drug	April 1, 2019
Pectus Deformity Repair	CDG	April 1, 2019
Rituximab (Rituxan® & Truxima®)	Drug	April 1, 2019
Self-Administered Medications List	Drug	April 1, 2019
Simponi Aria® (Golimumab) Injection for Intravenous Infusion	Drug	April 1, 2019
Stelara® (Ustekinumab)	Drug	April 1, 2019
Thermography	Medical	April 1, 2019
Trogarzo™ (Ibalizumab-Uiyk)	Drug	April 1, 2019

Note: The inclusion of a health service (e.g., test, drug, device or procedure) on this list does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information in this bulletin and the posted policy, the provisions of the posted policy prevail.

Copay Assistance – Amgen card conversion

COA 5/23/19 CAN Call with focus on patient assistance programs

May 23rd call information: 2:00 ET **Video and audio:** https://coacancer.zoom.us/j/917582549
Audio only: +16699006833,,917582549#

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Disclaimer: These updates provide coding and reimbursement related news and guidance. The distribution by ASCOM does not render legal advice. Practices should consult with individual payers, your local Medicare carrier, or CMS to obtain further clarification and assistance