FDA Hematology/Oncology Approvals & Safety Notifications since last meeting

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

2018

- FDA approved talazoparib (TALZENNA, Pfizer Inc.), a poly (ADP-ribose) polymerase (PARP) inhibitor, for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2 negative locally advanced or metastatic breast cancer. Patients must be selected for therapy based on an FDA-approved companion diagnostic for talazoparib. More Information. October 16, 2018.

- FDA approved emicizumab-kxwh injection (HEMLIBRA, Genentech, Inc.) for prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients (ages newborn and older) with hemophilia A (congenital factor VIII deficiency) with or without factor VIII (FVIII) inhibitors. More Information. October 4, 2018.


- FDA approved dacomitinib tablets (VIZIMPRO, Pfizer Pharmaceutical Company) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test. More Information. September 27, 2018.

- FDA granted regular approval to duvelisib (COPIKTRA, Verastem, Inc.) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. In addition, duvelisib received accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. More Information. September 24, 2018.

- FDA approved moxetumomab pasudotox-tdfk (LUMOXITI, AstraZeneca Pharmaceuticals LP), a CD22-directed cytotoxin indicated for adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). More Information. September 13, 2018.

- FDA approved pembrolizumab (KEYTRUDA, Merck & Co., Inc.) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, non-squamous non-small cell lung cancer (NSqNSCLC), with no EGFR or ALK genomic tumor aberrations. More Information. August 20, 2018.

- FDA updated the prescribing information for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq. More Information. August 16, 2018.

- FDA granted accelerated approval to nivolumab (Opdivo, Bristol-Myers Squibb Company Inc.) for patients with metastatic small cell lung cancer (SCLC) with progression after platinum-based chemotherapy and at least one other line of therapy. More Information. August 16, 2018.


- FDA approved mogamulizumab-kpkc (Poteligeo, Kyowa Kirin, Inc.) for adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. More Information. August 8, 2018.

- FDA approved lusutrombopag (Mulpleta, Shionogi Inc.) for thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure. More Information. July 31, 2018.
- FDA approved iobenguane I 131 (AZEDRA, Progenics Pharmaceuticals, Inc.) for adult and pediatric patients (12 years and older) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who require systemic anticancer therapy. More Information. July 30, 2018.


- FDA expanded the indication for ribociclib (Kisqali, Novartis Pharmaceuticals Corporation) in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. More Information. July 18, 2018.


- FDA has limited the use of Tecentriq and Keytruda for patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing therapy. More Information. June 19, 2018.

- FDA approved encorafenib and binimetinib (BRAFTOVI and MEKTOVI, Array BioPharma Inc.) in combination for patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test. More Information. June 27, 2018.

- FDA granted accelerated approval to pembrolizumab (Keytruda, Merck) for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. More Information. June 13, 2018.


- FDA approved pembrolizumab (Keytruda, Merck and Co. Inc.) for patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test. More Information. June 12, 2018.

- FDA granted regular approval to venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) for patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy. More Information. June 8, 2018.

- FDA approved methoxy polyethylene glycol-epoetin beta (Mircera, Vifor Pharma Inc.) for the treatment of pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. More Information. June 7, 2018.

- FDA approved Fulphila (pegfilgrastim-jmdb, Mylan GmbH) as a biosimilar to Neulasta (pegfilgrastim, Amgen, Inc.) to decrease the chance of infection as suggested by febrile neutropenia in patients with non-myeloid cancer who are receiving myelosuppressive chemotherapy that has a clinically significant incidence of febrile neutropenia. More Information. June 4, 2018.

**Medicare Fee Schedules**

**July and Oct 2018 Quarterly Drug file updates and NDC/HCPCS crosswalk files** -
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2018ASPFiles.html
July and Oct 2018 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

Oct 2018 Quarterly OPPS update:  https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-
MLN/MLNMattersArticles/downloads/MM10923.pdf

Biosimilar to Neulasta

![Image](https://www.palmettogba.com/palmetto/providers.nsf/ls/Railroad%20Medicare~AX4PBH2420?opendocument)

Policy Updates

Local Coverage Determination (LCD):

Octreotide Acetate for Injectable Suspension (Sandostatin LAR® depot) (L33438)
ICD10 Changes
https://www.cms.gov/medicare-coverage-database/details/lcd-
details.aspx?LCDId=33438&ContrId=381&ver=28&ContrVer=1&CntrctrSelected=381*1&Cntrctr=381&name=&DocTy
pe=Future&s=34%7c48%7c53%7c58&bc=AggAAAAQAAAAA&

Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L37176)
ICD10 & HCPCS changes
https://www.cms.gov/medicare-coverage-database/details/lcd-
details.aspx?LCDId=37176&ver=29&CntrctrSelected=381*1&Cntrctr=381&name=&DocType=Future&s=34%7c48%7c
53%7c58&bc=AggAAAAQAAAAA&

ESA – reminder about Palmetto GBA’s statement in March regarding ESA policy
https://www.palmettogba.com/palmetto/providers.nsf/DocsR/JJ-Part-B~AWUJZP7856
On January 18, 2018, CMS released Change Request (CR) 10318, Transmittal 2005 titled, “ICD-10 and Other Coding
Revisions to National Coverage Determinations (NCDs)”; it contains the latest coding instructions for CMS NCDs. We
are bringing the following NCDs to your attention.

NCD 110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer
Business requirement (BR) 10318.10 specifically addresses coding changes and is in process of CMS’ review. Until this
review is complete and CMS makes a final determination, the A/B MACs will not implement the edits contained in this
CR. The A/B MACs will also reprocess any claims that were processed in error from January 1, 2018, that were processed
with the additional codes included in CR 10318 as not payable with the EC modifier.

Denosumab (Prolia and Xgeva)
Palmetto GBA OPPS setting has recently started pre-pay audit reviews on these drugs.
Railroad Medicare announced they are performing post pay audits on these drugs.
https://www.palmettogba.com/palmetto/providers.nsf/ls/Railroad%20Medicare~AX4PBH2420?opendocument
E/M Weekly Tip: Cloning (Chief Complaint (CC), History of Present Illness (HPI), Review of Systems (ROS) and Examination)  Always document the Chief Complaint (CC) and History of Present Illness (HPI) based on the patient's description on that day. Never copy it from a previous visit. Only use the Review of Systems (ROS) and examination that is relevant to that day's visit.


Medical Review Reason Code Crosswalk

OPPS setting - No Cost Drug items –
Medicare Claims Processing Manual Chapter 32 - Billing Requirements for Special Services 67.2 – Institutional Billing for No Cost Items (Rev.4013, Issued: 03-30-18, Effective: 01-01-09, Implementation: 06-29-18) Generally speaking, institutional, providers should not have to report the usage of a no cost item. However, for some claims (e.g., hospital Outpatient Prospective Payment System (OPPS) claims), providers may be required to bill a no cost item due to claims processing edits that require an item (even if received at no cost) to be billed along with an associated service (e.g., a specified device must be reported along with a specified implantation procedure). For OPPS claims, when a drug is provided at no cost, claims processing edits prevent drug administration charges from being billed when the claim does not contain a covered/billable drug charge. Therefore, for drugs provided at no cost in the hospital outpatient department, providers must report the applicable drug HCPCS code and appropriate units with a token charge of less than $1.01 for the item in the covered charge field and mirror this less than $1.01 amount reported in the noncovered charge field. Providers must also bill the corresponding drug administration charge with the appropriate drug administration CPT or HCPCS code. For OPPS claims, providers must report a token charge of less than $1.01 for the item in the covered charge field, along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service requiring a device. For more information on billing no cost items under the OPPS, refer to Chapter 4, §20.6.9 and 61.3.1 of this manual.

2019 Medicare Part A and B deductibles and premiums
Here are three things to know:
1. Medicare Part A, which covers inpatient hospital, skilled nursing facility and some home healthcare, is premium-free for 99 percent of Medicare beneficiaries. Their Part A inpatient deductible is $1,364 for 2019, up $24 from this year.
2. The standard monthly premium for Medicare Part B will be $135.50 for 2019. That’s up from $134 this year for coverage spanning physician services, outpatient hospital care, some home healthcare services and durable medical equipment.
3. The annual deductible for Medicare Part B beneficiaries is $185 for next year, up $2 from 2018.

https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance

**Medicaid**

**United Healthcare**

Effective Feb. 1, 2019, Optum, an affiliate company of UnitedHealthcare, will begin managing prior authorization requests for outpatient injectable chemotherapy and related cancer therapies: • This change applies to UnitedHealthcare Commercial members with a cancer diagnosis. Any active prior authorizations requested through the former process will remain in place. Any active prior authorizations requested via the former process will remain in place. To submit an online request for prior authorization through the new process, sign in to Link and access the Prior Authorization and Notification tool. Then select the “Radiology, Cardiology + Oncology” box. After answering two questions about the state you work in, you’ll be directed to a new website to process these authorization requests.

Prior authorization/notification requests for UnitedHealthcare Oxford and Medicare members will continue to be requested though the existing eviCore process until future notice.

Prior authorization will continue to be required for: • Chemotherapy and biologic therapy injectable drugs (J9000 – J9999), Leucovorin (J0640) and Levoleucovorin (J0641) • Chemotherapy and biologic therapy injectable drugs that have a Q code • Chemotherapy and biologic therapy injectable drugs that have not yet received an assigned code and will be billed under a miscellaneous Healthcare Common Procedure Coding System (HCPCS) code • Colony Stimulating Factors: – Filgrastim (Neupogen®) J1442 – Filgrastim-aafi (NivestymTM) Q5110 – Filgrastim-sndz (Zarxio®) Q5101 – Pegfilgrastim (Neulasta®) J2505 – Pegfilgrastim-jmdb (FulphilaTM) Q5108 – Sargramostim (Leukine®) J2820 – Tbo-filgrastim (Granix®) J1447 • Denosumab (Brand names Xgeva and Prolia): J0897

Prior authorization will be required when adding a new injectable chemotherapy drug or cancer therapy to an existing regimen.

**Reimbursement Policy**

**Policy Update**

**Claims Requiring Additional Documentation**

*(Policy 06-031, effective 03/01/19)*

Professional providers and facilities are required to submit additional documentation for adjudication of applicable types of claims. If the required documentation is not submitted, the claim may be denied. Healthy Blue may request additional documentation or notify the provider or facility of additional documentation required for claims, subject to contractual obligations.

Effective March 1, 2019, if an itemized bill is requested and/or required, then it must include the appropriate revenue code for each individual charge.

For additional information, please review the Claims Requiring Additional Documentation reimbursement policy by going to www.HealthyBlueSC.com and selecting Providers.
Coordinated Commercial Reimbursement Policy Announcement

Whenever possible, UnitedHealthcare will make every effort to organize reimbursement policy updates into fewer articles to make it easier to review.

UnitedHealthcare remains committed to early, frequent, and transparent communication with care providers about our ongoing relationship. The chart below contains an overview of the policy changes and their effective dates for the following new policy: Discarded Drugs and Biologics Policy, Professional and Facility.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Effective Date</th>
<th>Summary of Change</th>
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</table>
| New Policy – Discarded Drugs and Biologics Policy, Professional and Facility | March 1, 2019 | • Payment may be made for the amount of drug or biological administered as well as the amount discarded up to the amount of the drug or biological as indicated on the single use vial or package.  
• The HCPCS code representing the amount administered should be submitted on one line and on a separate line the HCPCS code with JW appended to represent the amount discarded should be submitted.  
• The JW modifier is not permitted when the actual dose of the drug or biological administered is less than the billing unit.  
• The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient, while minimizing any wastage.  
• Modifier JW is not permitted to identify discarded amounts from a multi-dose vial (MDV).  
• The amount of the drug administered as well as the discarded drug or biological must be documented in the patient's medical record.  
• This policy applies to professional (1500 form) and outpatient claims (UB04). |

Reimbursement Policy Name Change UnitedHealthcare is currently working to better align our reimbursement policy titles to support the Centers for Medicare & Medicaid Services naming conventions and simplify searching for policies under multiple lines of business. UnitedHealthcare Commercial Plans “Assistant Surgeon Policy” and UnitedHealthcare Medicare Advantage Plans “Surgical Assistant Services Policy” will change to “Assistant-at-Surgery Services Policy” starting Dec. 1, 2018. This name change will not change the policy intent or the procedure codes eligible for reimbursement.

Billing for Intravenous and Subcutaneous Immune Globulin and Remicade® We want to inform care providers about a billing issue for Intravenous (IV) and Subcutaneous (SC) Immune Globulin (IG) and Remicade® (IV) affecting outpatient facilities. We’ve received some claims related to UnitedHealthcare commercial plans and UnitedHealthcare Community Plan without the appropriate ICD-10-CM diagnosis billing codes as listed in UnitedHealthcare Medical Benefit Drug policy guidelines. Claims will be reviewed to help ensure the condition treated with these medications is consistent with the Medical Benefit Drug Policy.
UnitedHealthcare Medicare Advantage Plans: The Care Improvement Plus Plan Name is Changing in 2019

All UnitedHealthcare Medicare Advantage plans that had a Care Improvement Plus plan name in 2018 will change to a UnitedHealthcare plan name on Jan. 1, 2019. This applies to all plans with a Care Improvement Plus plan name in Arkansas, Georgia, Missouri, South Carolina, Texas and Wisconsin. For specific plan name changes, please refer to the chart below.

How Does This Change Affect Care Providers?

The impact of this change on care providers is minimal. The UnitedHealthcare Administrative Guide and UnitedHealthcare Participation Agreement will continue to be your primary resources. Care providers may notice that starting Jan. 1, 2019, members will have the new UnitedHealthcare plan name on their ID card.

How Does This Change Affect Members?

Starting Jan. 1, 2019, impacted members will have the new UnitedHealthcare plan name on their ID card. They will also see the change in their Annual Notice of Change (ANOC). Members don't have to take any action as a result of this name change.

<table>
<thead>
<tr>
<th>State(s)</th>
<th>2018 Plan Name</th>
<th>2019 Plan Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR, GA, MO, SC, TX</td>
<td>Care Improvement Plus Medicare Advantage</td>
<td>UnitedHealthcare MedicareComplete Choice</td>
</tr>
<tr>
<td>AR, GA, MO, SC, TX</td>
<td>Care Improvement Plus Silver Rx</td>
<td>UnitedHealthcare Medicare Silver</td>
</tr>
<tr>
<td>AR, GA, MO, SC, TX</td>
<td>Care Improvement Plus Gold Rx</td>
<td>UnitedHealthcare Medicare Gold</td>
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<tr>
<td>AR, GA, MO, SC, TX</td>
<td>Care Improvement Plus Dual Advantage</td>
<td>UnitedHealthcare Complete Choice</td>
</tr>
<tr>
<td>WI</td>
<td>Care Improvement Plus Gold Rx</td>
<td>UnitedHealthcare MedicareComplete Assist</td>
</tr>
<tr>
<td>WI</td>
<td>Care Improvement Plus Medicare Advantage</td>
<td>UnitedHealthcare MedicareComplete Open Premier</td>
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<td>WI</td>
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</tr>
</tbody>
</table>

UnitedHealthcare Medicare Advantage Policy Guideline Updates

The following UnitedHealthcare Medicare Advantage Policy Guidelines have been updated to reflect the most current clinical coverage rules and guidelines developed by the Centers for Medicare & Medicaid Services (CMS). The updated policies are available for your reference at [UHCprovider.com > Policies and Protocols > Medicare Advantage Policies > Policy Guidelines](https://uhcprovider.com).

Chemotherapy for Colorectal Cancer (NCD 110.17)
Apheresis (Therapeutic Pheresis) (NCD 110.14)
Camptosar® (Irinotecan)
Eloxatin® (Oxaliplatin)
Erbitux® (Cetuximab)
Halaven® (Eribulin Mesylate)
Intravenous Iron Therapy (NCD 110.10)
Jevtana® (Cabazitaxel)
Blood, Blood Products and Related Procedures and Drugs
Breast Reconstruction Following Mastectomy
Genetic Testing
Medications/Drugs (Outpatient/Part B)

**Updated Healthcare Reimbursement Policies**

**Update on Injection and Infusion Services Policy**

In the September Network Bulletin, an update to the Injection and Infusion Services Policy was announced. The change involved a CPT® coding requirement that allowed only therapeutic infusion codes (96365 and 96369) to be reimbursed when reported with J3380 Vedolizumab/Entyvio, J1029 Abatacept/Orencia, J3250 Tocilizumab/Acetamino and/or J1602 Golimumab/Simponi instead of chemotherapy infusion codes (96413 and 96415). This planned change to the policy is undergoing additional evaluation. The change will not be effective on Dec. 1, 2018 as previously announced.

**BCBS State** – site of care restrictions on some drugs beginning in January 2019. May prevent some treatments in hospital outpatient setting.

**BCBS**

1. Starting on 08/27/2018 BlueCross BlueShield of South Carolina begin sending out erroneous 251 edits on submitted claims. BlueCross BlueShield of South Carolina is working to resolve the underlying issue which has caused the erroneous 251 edits and will send out an update when the issue is resolved. Any claim
that received a 251 edit during the time of the issue will need to be resubmitted. Be advised that some 251 edits will be valid after resubmission. BlueCross BlueShield of South Carolina apologies for the inconvenience this is causing. (251 has something to do with ID not on file)

Coding updates

ICD-10-CM Official Guidelines for Coding and Reporting FY 2019

https://www.cdc.gov/nchs/icd/icd10cm.htm


What’s New, Different, or Deleted with ICD-10-CM Codes in 2019

October 1, 2018, ICD-10-CM code changes are the third mandated updates since ICD-10 codes went live on October 1, 2015.

For the 2019 updates, there are 92 new codes, 22 deleted codes, and 8 revised codes for eye-specific patient encounters occurring from October 1, 2018, through September 30, 2019. 2019 ICD-10-CM codes changes affect Chapter 2 (Neoplasms), Chapter 6 (Diseases of the Nervous System), and Chapter 7 (Diseases of the Eye and Adnexa).

The guidelines include updated language conventions to improve coding accuracy. Per guideline I.C.1.15, “with” or “in” should be interpreted to mean “associated with” or “due to” when they appear in the Alphabetic Index (either under a main term or subterm), a code title, or an instructional note in the Tabular List.

Some notable chapter-specific guideline changes include:

- Chapter 1, Sepsis due to postprocedural infection
  - Per guideline I.C.1.5.b, when coding for a postprocedural infection, coders should look to 2019 ICD-10 subcategories T81.40- to T81.43- (infections following a procedure) or within subcategories O86.00 to O86.03 (Infections of an obstetric surgical wound) to identify the site of the infection. An additional 2019 code should be assigned to identify sepsis following a procedure (T81.44-) or sepsis following an obstetrical procedure (O86.04-). Coders must select an additional ICD-10 code to identify the infectious agent.

- Chapter 2, Current malignancy versus personal history of malignancy
  - The 2019 guidelines clarify reporting for a current malignancy versus a personal history of malignancy. Per guideline I.C.2.m., subcategories Z85.0- through Z85.7- should be assigned for the former site of a primary malignancy, not the site of a secondary malignancy.

- Chapter 5, Factious disorder
  - A new section was added on reporting factious disorder, a psychological condition that will be added to ICD-10-CM on October 1.

- Chapter 15, Drug use during pregnancy, childbirth and the puerperium
  - A new subsection was added to guideline I.C.15.l.c. (Drug use during pregnancy, childbirth and the puerperium) for any pregnancy case when a mother uses drugs during the pregnancy or postpartum. This subsection was added to clarify reporting of new, more specific 2019 codes for drug use during pregnancy.

- Chapter 18, Glasgow coma scale
  - Guideline I.C.18.e now notes that individual or total Glasgow coma scale scores should not be reported for patients who were sedated or in a medically induced coma.
Coders should familiarize themselves with these changes, which will impact diagnosis reporting from October 1, 2018, through September 30, 2019.

2019 HCPCS Codes won’t be available with CMS until early November. The alphanumeric index and the table of drugs will also be posted to the CMS website in early November. The website address is https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html.

The 2019 Open Enrollment Period for Health Insurance Starts Nov. 1 and Runs Through Dec. 15

The open enrollment period for purchasing private insurance on the Marketplace begins on November 1 and runs through December 15, 2018. The ACA’s income-based subsidies on premiums are still intact, which means many South Carolinians will be eligible for zero-premium bronze plans on the Marketplace. Roughly 90% of enrollees will receive some form of subsidy, and the average tax credit for a South Carolinian in 2018 was $488 per month.

Coverage will be available during the same abbreviated 45-day window that the federal government allowed last year with fewer resources for state navigators and enrollment assistance.

This enrollment season saw South Carolina’s funding for open enrollment cut from $1.1 million to $300,000, and the allowance of “short-term plans,” which may deny coverage for pre-existing conditions and institute lifetime caps and other restrictions on coverage.

The Kaiser Family Foundation recently reported that, of South Carolina’s 439,000 uninsured, some 179,000 are eligible for Affordable Care Act Marketplace subsidies. For all those who need to sign up, help is free and available. Call 888-998-4646 or go to signupsc.org and experts will guide SC residents through the process to find out what they qualify for and what options are available that best fit their needs.

Prepared by: Liza Owens West with contributions by Lynn Hollifield and Samantha Lee

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.