

NUBC Meeting
August 13-14, 2019
American Medical Association
330 N. Wabash Ave
47th Floor
Chicago, IL 60611
TENTATIVE AGENDA
(as of 8/06/19)

August 13, 2019 - Open NUBC Meeting

(Dress: Business Casual)

- | | |
|----------------|---|
| 1:00 - 1:15 pm | Welcome and Introductions of Current and New Members |
| 1:15 - 1:30 | Review and Approval of the July 18, 2019 Conference Call Minutes |
| 1:30 - 2:45 | <u>Change Requests</u> <ul style="list-style-type: none">• Gene Therapy - New Revenue Code and Value Code (Attachment 1)• Allogeneic Stem Cell Transplant Claims - New Condition Code and Value Codes (Attachment 2) |
| 2:45 - 3:00 | Break |
| 3:00 - 4:30 | <u>Change Requests - Continued</u> <ul style="list-style-type: none">• Update Revenue Code 0278 - Other Implant (Attachment 3)• Update Revenue Category 017x - Nursery (Attachment 4)• Modify Situational Rule - Referring Provider (UB-04: FL 78-79; 837: Loop ID 2310F) (Attachment 5)• Other State Issues |

(OVER)

**NUBC Meeting
August 13-14, 2019
American Medical Association
330 N. Wabash Ave
47th Floor
Chicago, IL 60611
TENTATIVE AGENDA
(as of 8/06/19)**

August 14, 2019 - Open NUBC Meeting

(Dress: Business Casual)

8:00 - 8:30 am Breakfast

8:30 - 10:00 Resume from July conference call: CMS Request for New Condition Codes for Service Facility Locations (Attachment 6)

NUBC/NUCC Joint Meeting

10:15 I. 2020 Meeting Planning

10:30 II. E&M Documentation Changes

11:00 III. NCVHS Visioning Session on the Standards Process (Attachment A)

11:30 IV. Appropriate Use Criteria for Advanced Diagnostic Imaging (Attachment B)

12:00 pm Lunch

NUCC Open Meeting

1:00 - 5:00 pm (Agenda available from NUCC)

CHANGE REQUEST

My name is Terri Rinker, and I'm the Chairperson of the Provider Roundtable (PRT). We are a group composed of providers who gather to provide substantive comments with an operational focus to CMS and other organizations such as NUBC.

The Provider Roundtable (PRT) includes representatives from 13 different health systems, serving patients in 20 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services, but do not have any specific financial relationship with vendors.

One of our members, and former chairman of the PRT is John Settlemyer. He is Assistant Vice President of Revenue Management at Atrium Health in Charlotte NC. He was present at the last NUBC meeting when cell therapy/CAR-T was discussed.

The PRT is asking if the following item can be added to the NUBC's August meeting agenda:

Request for revenue code 0892 in the 089x series for "Special Processed Drugs – FDA Approved Gene Therapy" which mirrors the existing 0891 for cell therapy products. Since there is now an FDA approved gene therapy (Zolgensma for pediatric patients with spinal muscular atrophy – SMA) and more are in the pipeline, we believe this additional revenue code is needed. Last August, the NUBC created the 089x series and only created 0891 for cell therapy because there were no approved gene therapies on the market. Now that there is one, the PRT believes it would be appropriate to release 0892 otherwise providers might inappropriately use 0891 or perhaps they would continue to use rev code 025x or 636 with an unlisted CPT code. If 0892 were created, it would be more appropriate. We are hoping this is a simple ask since the category 089x exists. In case it helps, we believe the info would read as follows:

0892: Special Processed Drugs - FDA Approved Gene Therapy(b) DRUGS/GENE THERAPY

(b) Charges for drugs and biologics for gene therapy requiring specific identification as required by the payer. If using a HCPCS to describe the drug, enter the HCPCS code in the appropriate HCPCS column.

Finally, we wonder whether it would make sense to **change value code 86** so that it is just for cell therapy (right now it's for cell and gene therapy) and then **create a new, separate value code for gene therapies** since these are fundamentally different and if there are different revenue codes (which there would need to be since 0891 is only for cell therapy), it seems reasonable that there would be a different value code for gene therapy...especially if payers would find it useful to receive acquisition cost for cell and gene therapies separately (so through different value codes).

Thank you for considering this and please let me know if you have any follow up questions.

Terri Rinker
Chairperson, Provider Round Table and
Revenue Cycle Director
Community Hospital Anderson
1515 N. Madison Ave
Anderson, IN 46011

ZOLGENSMA

- ZOLGENSMA is a prescription gene therapy used to treat children less than 2 years old with spinal muscular atrophy (SMA). ZOLGENSMA is given as a one-time infusion (on an outpatient basis) into the vein. ZOLGENSMA was not evaluated in patients with advanced SMA.
- SMA is a rare, genetic neuromuscular disease caused by a defective or missing *survival motor neuron 1 (SMN1)* gene. Infants who do not have a functional *SMN1* gene lose the motor neurons responsible for muscle functions such as breathing, swallowing, speaking and walking. In its most severe form, SMA can lead to permanent ventilation or death by age 2.
- ZOLGENSMA works to halt disease progression by replacing the defective or missing *SMN1* gene. It is administered as a single, one-time infusion.
- FDA approved ZOLGENSMA on May 26, 2019. At the time of approval, the cost of ZOLGENSMA was \$2.125 million, making it the world's most expensive drug.
- This drug would be more for the Medicaid population.
- There are a number of gene therapies in the pipeline that would impact the older population, though they are likely several years out.
- This drug is being covered by commercial health plans and the manufacturer is agreeing to an outcome based installment payment. The claims can be submitted or adjusted at the stages of the installment.
- As of now, there is not a specific drug/biologics HCPCS assigned. Since this is a very new drug, specific HCPCS code and more info on cost, coverage, etc. will unfold.
- Currently valid HCPCS for the drug itself:
 - C9399 for new FDA approved drugs, biologicals and radio pharmaceuticals with no specific HCPCS code assigned yet
 - J3590 is for *Unclassified biologics Drugs administered other than oral method*
 - J3490 for non-coded drugs unlisted NDC number
- The administration codes would be simple infusion codes.
- There are specific diagnosis codes associated with the administration of this drug. The following ICD-10-CM codes would be appropriate with Zolgensma:
 - G12.0 Infantile Spinal Muscular Atrophy, type 1 (Werdnig-Hoffmann)
 - G12.1 Other inherited spinal muscular atrophy
 - G12.9 Spinal muscular atrophy, unspecified

July 17, 2019

Todd Omundson
Secretary, NUBC
American Hospital Association
155 N. Wacker Dr. Suite 400
Chicago, IL 60606

Re: NMDP Request for a new condition code and two new value codes to improve visibility into allogeneic SCT claims for NUBC August 2019 Meeting

Dear Mr. Omundson:

The National Marrow Donor Program (NMDP)®/ Be The Match® manages the largest and most diverse marrow registry in the world. For the thousands of Americans diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. Today, there are 19 million U.S. volunteers listed on the registry and willing to donate, in addition to more than 249,000 cord blood units, making the cure available through transplant a reality for thousands of Americans each year.

As the steward of this critical public health program, we work to identify and eliminate barriers faced by those patients in need of one of these life-saving transplants. Assisting with both transplant center and third-party payer matters is a function of our Office of Patient Advocacy. NMDP partners with nearly 200 hospital transplant programs across the country in assisting them with efforts to improve access to transplant.

We are asking for the addition of a new condition code and two new value to help payers, researchers and providers better understand and to improve the consistency of claims data regarding stem cell transplant (SCT) cases. The SCT recipient claims are often challenging to understand because they lack consistent information regarding donor charges and services. The requests below will enable all of information to be on the recipients claim and continue to allow flexibility in how different payers process donor costs including allowing separate donor claims billed under recipient names. Because there are varying ways that claims submission/billing is allowed by different payers, it is not possible to fully understand the donor costs associated with a recipient's SCT claim. It is impossible to understand if any or all donor charges are being reported on the recipient's claim or not and even when they are, we have no way of understanding why donor charges vary so much (i.e., multiple potential related donors may be worked up even in cases when ultimately unrelated donor cells are used).

As you know, NUBC's goal is to achieve administrative simplification as outlined in the Health Insurance Portability and Accountability Act (HIPAA) of 1996. We believe the requests below would better achieve administrative simplification based on our experience in having completed numerous SCT claims reviews.

NMDP's request of NUBC

Our request includes providing for improved data and visibility into allogeneic SCT claims. More information on this issue is provided below:

- Even when coded correctly, the donor charges associated with a related SCT recipient may vary significantly based on the number of donors “worked up” until a choice was made on the best related donor;
- For unrelated SCTs, there may have been expenses for services required to work up related donors until all related donors are “ruled out” (i.e. not an appropriate donor candidate for a transplant) and the clinician then decides to obtain unrelated donor cells from the NMDP;
- Insight into what often are significant case cost differences associated with donors is not possible with current claim transaction sets especially given that billing rules legitimately differ between Medicare and some commercial payers; and
- Additional information and visibility into case cost differences could be significantly improved if NUBC were to grant additional values to be reported on SCT recipient’s claims.

1. Request New Condition Code:

Some commercial payers (not Medicare) allow hospitals to bill for search and procurement costs for related donors separate from the transplant episode reported on the recipient’s claim. A condition code indicating that the claim being submitted is solely for donor charges, i.e., the cost of finding and working up potential related SCT donor candidates would clarify which claims are related to search and procurement of donor cells (donor services) vs. costs related to the care of the patient. Often the various department charges on these claims have not been reported with revenue code 0815. Having a condition code will ensure that the payer understands the claim is for SCT donor services.

This would be reported on claims billed under the recipient’s name, but where the claim is for and/or includes donor services and would be used for those payers that allow donor claims to be submitted under the recipient’s name and ID as they occur and not required holding and reporting in the recipient’s transplant claim as Medicare requires. Per NUBC, the revenue code that must be used to report all SCT donor services is 0815. Adding a condition code for payers other than Medicare would allow for identification of donor claims/charges being billed under the recipient’s insurance in real-time and would also allow consistency edits that the donor charges should be billed under revenue code 0815 even if they appear on separate claims.

2. Request Two New Value Codes:

The first value code would be to communicate how many related donors were worked up prior to transplant on the recipient’s SCT claim. This value could be zero, 1 or more and would be reported even on an unrelated donor recipient’s claim to report that “X number” of related donors were “worked up” (tested, typed, evaluated) prior to ultimately going with unrelated donor cells for an unrelated allogeneic SCT. A zero would communicate that all the donor costs reported are exclusively for unrelated donor cells purchased from NMDP.

Often, when transplant patients are searching for a donor, relatives are tested at the same time the transplant center (TC) searches the NMDP registry for an unrelated donor. If the related donors are “ruled out” the TC still incurs the cost of working up those potential related donors. The value code would help explain why a claim’s revenue code 0815 charges might be much higher when the hospital treats an unrelated SCT patient since the revenue code 0815 charges should represent all of the donor work-up/HLA charges (related and

unrelated) + the NMDP invoice charges; the totality of which represents the full donor related costs for this transplant recipient.

The second value code would be to report the total donor charges for the recipient's transplant episode on the recipient's transplant claim which may or may not match the revenue code line item 0815 on the claim since there could be situations where a payer (not Medicare) allows the donor charges to be billed separately from the recipient's transplant claim. As described above, some commercial payers allow separate donor claims to be billed under the recipient's name as they occur rather than having them held the way Medicare requires, but there is no way to know today (for example when looking in Vizient data on recipients claims) what the total donor charges were that contributed to the entire transplant case because there may have been separate donor claims.

This new value code would report the sum total of all donor charges including charges billed on claims other than the recipient's transplant claim. In other words, revenue code 0815 charges on a Medicare claim should match the exact dollar amount reported in the value code because Medicare requires all donor charges to be billed on the recipient's SCT claim. For commercial payers, the amount in this value code field may or may not be greater than the 0815 charges on the recipient's SCT claim. Note that this is similar to the current value code 50 that some payers ask to be reported. If the value reported is greater than the 0815 charges on the recipient's transplant claim, then that would tell us other donor claims were incurred and billed at a separate point in time. It allows researchers and payers to know the total value of donor costs for the recipient but continues to allow flexibility by payer for billing donor claims as needed. If the dollar amount was the same for example on commercial claims, then it tells us that the payer follows the Medicare rule about having to hold charges.

We believe these additional codes will help payers, researchers, and providers more accurately identify the costs involved in SCT. It will allow providers to better ensure they are billing correctly by allowing internal checks and balance edits to be applied when billing SCT claims. Due to variations in billing donor services between Medicare and those payers that follow Medicare rules versus other payers that allow separate donor claims, most SCT billing is handled manually and these new values will allow edits on claims to better ensure complete and consistent billing and adjudication by payers. Being able to extract total costs associated with donor search and procurement will help payers and providers make more informed decisions about the value of transplant and also provide needed information toward those that pay via episodes. We respectfully request the NUBC review this proposal at the Aug. 13-14 meeting.

Please feel free to reach out to me either by email at sleppke@nmdp.org or by phone at 763-406-8522 if you have any questions.

Sincerely,

Susan N. Leppke, MPH
Director, Health and Public Policy

NUBC Minutes Excerpts related to Implants (Revenue Code 0278)

November 7 - 9, 2001 Meeting Minutes

Action: Approved

There was no opposition to adding the language in the paragraph below to the UB-92 Manual. Descriptive language on experimental devices will be added; radioactive seeds will be added to the list; and, a note will be made that the list is not all-inclusive. Mr. Arges commented that no implementation date is necessary because the action is a clarification of codes already in place. Education will be necessary. The NUBC will contact the representatives from the managed care companies about this change so they can communicate to their constituencies on the use of these codes. Ms. Brown will write up an educational piece for insertion in the Coding Clinic HCPCS newsletter and for possible posting to the NUBC website.

Add footnote (a) to revenue code 278 as follows:

(a) Implantables:

That which is implanted, such as a piece of tissue, a tooth, a pellet of medicine, or a tube or needle containing a radioactive substance, a graft, or an insert. Also included are liquid and solid plastic materials used to augment tissues or to fill in areas traumatically or surgically removed. An object or material partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes.

Examples of Other Implants (not all-inclusive):

Stents, artificial joints, shunts, grafts, pins, plates, screws, anchors, radioactive seeds

Experimental devices that are implantable, and have been granted an FDA Investigational Device Exemption (IDE) number, should be billed with revenue code 624.

August 3-4, 2004 Meeting Minutes

d. Revenue Code 0278 (not on written agenda)

The NUBC received a request for clarification on Revenue Code 0278 about whether a skin graft from human skin or regenerated tissue is considered an implant. Some of the confusion stems from the definition of a “pass through” by CMS. Ms. Raines said that from a Medicare point of view, some of the skin graft materials are considered biologicals and should be billed under Revenue Code 0636 (with a HCPCS), but the definition in the UB Manual indicates that “tissue” should be billed under 0278. The committee is seeking clarification of this issue. CMS will investigate and respond back.

March 31 and April 1, 2009 Meeting Minutes

4. Reimbursement for Supplies and Materials under Revenue Code 0278

We have received questions on what should be considered an implant and what should be bundled with an implant. Many thought that our current definition needed some improvement. They want us to consider review criteria that could help people differentiate implants from non-implants. The agenda also included a statement from Aetna that describes how they define an implantable device. Mr. Arges felt that the first two points in the Aetna definition were pretty good; he also noted that they included another point -- a time line of six months. He mentioned that the NUBC has never supported a particular time element for an implant remaining in a body. He asked how people feel about our current definition and whether it should be modified/improved.

Ms. Birkenshaw referred to FDA verbiage: “A permanently implantable device is a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended to be used for temporary purposes or which is intended for explantation.”

Mr. Arges read another definition attributed to the FDA for implantable device: “device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more.” [21 CFR 812.3(d)].

Mr. Arges went on to read how Aetna defines an implantable device: “For the purposes of our agreement, an implantable device is: 1) a biocompatible mechanical device or biomedical material that serves to replace a biological structure, or 2) a device or biomedical material that supports and/or enhances the command and control of a biological process. Furthermore, an implantable device is only one that is intended to remain in the body for a minimum of six months.”

Ms. Reep remarked that we must be sure that we separate devices from implants; not all devices are implanted. In addition, if we delve into a definition that contains a period of permanence, then we’ve got to be able to capture the other types of devices that are implanted without an indication of permanence. She didn’t think these types of items fit very well under sterile supply and the other items within the 027x category.

Ms. Carnevale didn’t believe that there should be anything mentioned with respect to time. For example, radiotherapy seeds have a limited life but are definitely implants. She indicated that they went back to Aetna and were able to get the 6-month rule withdrawn.

The committee noted that FDA definitions are not static -- they are fluid depending on what is going on in the industry. Ms. Reep thought that if we go with something containing a time frame (like the second FDA definition), we should then consider another revenue code to address other devices. Some devices intended to be permanent end up being temporary if they have to be removed for some reason.

Ms. Carnevale indicated that her facility has payer contracts that define implants differently. Most of the contracts do not consider catheters, guidelines, etc. to be implants. In one contract,

anything over \$500 is charged to “other implants” (0278). Normally hospitals and plans tend to negotiate these on their own terms; creating a blanket policy that is too restrictive could negate many of the contract terms. Mr. Arges commented that we want a level of consistency around the reporting because there are instances, for many organizations, where there is simply no contract. He also thought that defining an implant based on a dollar amount is improper.

Sometimes all the parts (screws, etc.) for an implant are packaged together by the manufacturer on one invoice. Ms. Carnevale does not bill the implant as a complete package. Their chargemaster has the ability to identify each part that is contained in the package, which is exploded into sterile supplies, implants, etc., and billed separately. However, not every hospital in the U.S. does it this way. Ms. Reep remarked that FL workers’ comp wants the implant billed as a single item particularly if it came packaged on a single invoice. It was noted that not everything in the package is used; but once the package is opened, it can’t be reused for another patient.

The committee discussed the meaning of the first part of the Aetna letter at length:

“We will no longer separately reimburse supplies/materials. We are aware that some facilities have customarily billed for supplies and materials under Revenue Code 278. However, consistent with the terms of your agreement with us, effective May 1, 2008, we will no longer reimburse separately for supplies/materials provided as part of a medical and/or surgical procedure.”

Some thought that this just meant that they would not pay supplies separately if billed under 0278; but they would still be billed in 0271, 0272, etc.

Ms. Merryweather liked Aetna’s implant definition except for the time frame. Ms. Pickett wondered where the term “biocompatible” came from. She argued that if we are going to tie something to a definition it should be something that is well represented in the literature, i.e., recognized by another source.

Mr. Arges commented that the real question for us is whether the current NUBC definition is adequate. Mr. Omundson thought the key element was whether or not there should be a timeline. CMS did not recommend a timeline in its final FY2009 IPPS rule (even though the NPRM had proposed a timeline). NUBC members were of the general opinion no time constraint should be added to the definition noting that it might be too limiting to accommodate advances in new technology.

Ms. St. Pierre asked whether the last part of our definition (“... inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes.”) would include urinary catheters. Catheters and guide wires are both inserted, but are they implants?

Mr. Omundson suggested adding some more examples and exclusions to our definition. For example, catheters that stay in the body are included; catheters that don’t remain are excluded. With respect to the current definition, Ms. Carnevale would not bill “a tube or needle” as an implant; however the radioactive substance in the needle would be billed.

In terms of verbiage, Ms. Reep offered “The NUBC is not recommending a time frame”, or “this definition does not allow for or set a time frame component”, or that “no timeframe is associated with the implant”, which is different than saying there is no timeframe. Members noted that other sources such as FDA have identified an intended timeframe; the NUBC does not want to override other sources like FDA.

Mr. Arges wondered if there should be a separate revenue code category for implantables, with subcategories for radioactive seeds, etc. This would not be an extension (062x), but an entirely new revenue category. He thought it would be best if we involved the health plans to help to determine whether this approach would be of any value. Ms. Burch asked whether pacemakers (0275) should be broadened to include other cardiac devices such as implantable defibrillators.

In terms of cost report implications, Ms. Reep noted that last year’s final rule indicated that “implantable devices charged to patients” could be easily redefined via adding another revenue code. A new revenue code would make it easier to track implants from an analytical viewpoint (e.g., the number of people that have implants vs. a supply item).

A discussion of the pros and cons of adding a new revenue code began. It was noted that all contracts would have to be redone. Because there is no urgency to create a new category, a longer lead-time could be allowed - -at least two-years. Some thought that the current definition was satisfactory and that cleaning it up and providing more examples may accomplish the same thing as creating a new code.

ACTION: Deferred

A request was made for the payer representatives to find out whether their members are satisfied with the adequacy of the current definition. They will inquire whether any of them have their own internal definition (similar to Aetna).

Ms. Raines also asked the payers to find out if any of them use language about “intent” (not a timeline) for the device to remain in the body. For example, Aetna indicates a six month period.

June 17, 2009 Conference Call Minutes
(Update to March 31 and April 1, 2009 Meeting Minutes)

4. Reimbursement for Supplies and Materials under Revenue Code 0278

Pat Burch went out to member companies of AHIP asking their opinions on whether time parameters should be included in the definition per our meeting in Baltimore.

Response #1

It probably wouldn't hurt to get it defined as much as possible because the only impact would probably be financial - e.g., whether the device implanted should be separately reported and/or reimbursed.

Response #2

- Yes, we believe the length of time the device is in the body should be part of the coding definition. The device must be permanent to be considered an implant.
- In general any revision/definitional change that more clearly differentiates implants from supplies would be beneficial, specifically as it pertains to Revenue Code 0278. Revenue Code 0278 has an overly broad description which allows hospitals to intermix supplies and implants. HCPCS "C" codes should not be defined as implants.
- Revenue Code 0275 -- Contractual concerns about expanding the definition to include "other cardiac devices"; could lead to increased financial liability.

In addition, we have received other (unsolicited) input on categorizing devices/implants/supplies that we will share at the August meeting.

The NUBC needs some more input from other health plans at this time; Mr. DeCrosta indicated that he will follow up with Blues plans.

August 11-12, 2009 Meeting Minutes

4. Medical/Surgical Supplies and Devices (Implant Definition)

Ms. Carnevale commented that her hospital uses the current NUBC definition in their contracting; it's broad enough to allow them to operate. She commented that all of their payers/contracts would be affected by a definitional change. Ms. Reep and FHA members support the current definition and oppose any attempt to add a time element. Ms. Lestina noted a surge in questions about what to include in 0278. People are adding items to 0278 that could be viewed as incidental to the procedure. She thinks we have a good definition; the problem is that it is just open enough for people to interpret it a little differently. She doesn't think that a timeline solves the problem; rather it's how you define what is incidental to the procedure vs. what is truly implantable.

Mr. Arges commented that any definitional change would be subject to even more debate. The one constant we heard is that people are generally comfortable with our definition.

Ms. Reep thinks the issue arises in contract situations where the implant is carved-out and paid differently. She noted that for worker's comp claims in Florida, they are defined as simply as anything billed with revenue code 0278.

ACTION: No changes to the 027x Implantable Definition

The NUBC decided to keep the definition as is until something that comes forward with a better definition that also has industry consensus.

Ms. Pickett remarked that each of the procedure coding systems currently in place define “implantable device” differently. She felt that the NUBC cannot be the arbiter of what is and what is not an implantable device; we don’t have the knowledge nor is it our role. She favored letting the provider make that determination with their payer. She acknowledged that this approach is somewhat counter to the intent of standardization, but she believes that this is outside of our scope. The NUBC agreed.

The NUBC advises that providers should bill the item the way they think is appropriate and argue their case with the payer if they get a denial. If you characterize this item as an implant and don’t have a payer disagreeing with you, there shouldn’t be a problem. Many providers have contracts that spell out what is included in 0278 and how it will be reimbursed.

April 9-10, 2019 Meeting Minutes

5. State and other Issues

Implants

Ms. Reep remarked that different payers are applying their own definition of implant. Some payers say it is not an implant unless it is expected to remain in the body for a year. Other payers say it is not an implant unless it is expected to remain in the body for 30 days (the FDA definition); some say 15 days. The NUBC definition makes no reference to a time horizon. There is also the issue of what exactly an implant is -- are radioactive seeds, nuts and bolts implants? She would like to adopt a good definition for an implant itself, irrespective of a time period. We need some consistency in definition so we don’t have providers billing Payer A as an implant and Payer B as a supply, etc. Therefore, she thinks we should go back and define/redefine implant. Florida has one payer that defined it three different ways over the course of a year. Ms. Carnevale agrees that it should be one definition. Each of her payer contracts define it differently. To her, the FDA’s definition seems most appropriate.

Mr. Omundson referred to FDA’s database of devices (GUDID). When reviewing the GUDID for high risk implants, the FDA has difficulty identifying what is an implant and what is not an implant.

Ms. Reep commented that perhaps the definition should be agreed to by contract. Absent an agreed upon definition with the payer, we could apply the FDA definition (expected to remain in the body for 30 days) so providers don’t bill differently based on payer. Ms. Kalland and others thought a standard definition would be beneficial.

Ms. Berger remarked that the NUBC definition says “An object or material partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes.” In Minnesota providers tend to follow CMS billing methodology; but CMS doesn’t have any prescriptive requirements for implantables because most of the time they are not paying for implants. She thinks questions around separate payment for implants are a part of the issue. CMS doesn’t have

to deal with that matter because they don't pay separately. She wondered what revenue category high priced single use catheters are reported. She thinks most providers put those into revenue code 0278, but they are not implants. They could do it because it is "an object or material partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes." She commented that definitely items other than implants are being reported in 0278. Ms. Reep added that payers are asking providers to not use 0278 for a pellet of medicine, even though it is included in the definition; this is another reason why we need a good definition.

Ms. Kocher understands the providers' concern, but she thinks that putting a time frame in the NUBC definition is crossing over the line of our purview. Time is a clinical question and the UB is not a clinical code set.

Ms. Ott thought that this is mainly a contractual issue, so even if we put 15 days in the definition, a provider and a payer could both agree that it should be 30 days. Ms. Reep commented that it's not necessarily contractual because she may be dealing with a payer with whom there is no contract. Ms. Carnevale thinks this is more of a coverage issue. If she has a non-contracted payer who wants to deny payment, they would appeal it; if it was a contractual issue they would fight it out with the payer.

Mr. Koopman read the FDA definition: "an implant is a device that is placed into a surgically or naturally formed cavity in the human body and is intended to remain there for a period of 30 days or more. In order to protect public health, FDA may determine that devices placed in subjects for shorter periods are also implants".

Mr. Omundson commented that for our definition, we could say that "no time limit is specified." Ms. Reep liked that idea and noted that this language was specifically mentioned in prior minutes.

Ms. Ott asked if was possible to incorporate some of what Mr. Koopman was referencing, putting it in the clinically appropriate language, with no defined time limit.

Mr. Omundson wanted to do a little more research on the NUBC's history with implants – what we did and why we did it.

ACTION: The NUBC agreed to table this topic to next conference call and draft up proposed language for discussion.

Effective Date: March 1, 2007
July 1, 2020
Meeting Date: 8/13/19

Form Locator 42
Page 14 of 59

027x Medical/Surgical Supplies and Devices (also see 062x, an extension of 027x)

Charges for supply items required for patient care.

SubC	Subcategory Definition	Standard Abbreviation	Unit	HCPCS
0	General Classification	MED-SUR SUPPLIES		
1	Non-sterile Supply	NON-STER SUPPLY		
2	Sterile Supply	STERILE SUPPLY		
3	Take Home Supplies	TAKEHOME SUPPLY		
4	Prosthetic/Orthotic Devices	PROSTH/ORTH DEV	Devices	
5	Pacemaker	PACEMAKER		
6	Intraocular Lens	INTRA OC LENS		
7	Oxygen - Take Home	O2/TAKEHOME		
8	Other Implant ^(a)	SUPPLY/IMPLANTS		Y
9	Other Supplies/Devices	SUPPLY/OTHER		

~~**Implantables:** That which is implanted, such as a piece of tissue, a tooth, a pellet of medicine, or a tube or needle containing a radioactive substance, a graft, or an insert. Also included are liquid and solid plastic materials used to augment tissues or to fill in areas traumatically or surgically removed. An object or material partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic purposes.~~

^(a)A device that is placed into a surgically or naturally formed cavity of the human body or on the surface of the body and intended to remain there for a period of time^(b).

Many implants are prosthetics, intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues. Some implants are made from skin, bone or other body tissues. Others are made from metal, plastic, ceramic or other materials.

^(b)Absent a contractually agreed upon definition of time with the payer, the FDA defined time period of 30 days or more is appropriate.

~~**Examples of Other Implants (not all inclusive):** Stents, artificial joints, shunts, grafts, pins, plates, screws, anchors, radioactive seeds.~~

Experimental devices that are implantable and have been granted an FDA Investigational Device Exemption (IDE) number should be billed with revenue code 0624.

Effective Date: July 1, 2020
Meeting Date:

Form Locator 42
Page 8 of 59

017x Nursery

Accommodation charges for nursing care to newborns and premature infants in nurseries.

SubC	Subcategory Definition	Standard Abbreviation	Unit	HCPCS
0	General Classification	NURSERY	Days	N
1	Newborn - Level I	NURSERY/LEVEL I	Days	N
2	Newborn - Level II	NURSERY/LEVEL II	Days	N
3	Newborn - Level III	NURSERY/LEVEL III	Days	N
4	Newborn - Level IV	NURSERY/LEVEL IV	Days	N
5-8	<i>RESERVED</i>			
9	Other Nursery	NURSERY-OTHER	Days	N

Notes: The levels of care correlate to the intensity of medical care provided to an infant and not the NICU facility certification level assigned by the state.

The level of care should be clinically evaluated on a daily basis, typically based on the resources provided to the infant. The assigned revenue code corresponds to the level of care determined during the daily evaluation. The levels of care and resulting revenue codes may, and likely will, fluctuate during the infant's stay in the facility.

Subcategories 1 - 4 for use by facilities with nursery services designed around distinct areas and/or levels of care. Levels of care defined under state regulations or other statutes supersede the guidelines below. For example, some states may have fewer than four levels of care or may have multiple levels within a category such as intensive care (NICU).

Level of Care	Capabilities
Level I Well Newborn Nursery (a)	<ul style="list-style-type: none"> • Provide neonatal resuscitation at every delivery. • Evaluate and provide postnatal care to stable term newborn infants. • Stabilize and provide care for infants born 35-37 weeks gestational age who remain physiologically stable. • Stabilize newborn infants who are ill and those born at < 35 weeks gestational age until transfer to a higher level of care.
Level II Special Care Nursery (b)	<p>Level I capabilities plus:</p> <ul style="list-style-type: none"> • Provide care for infants born ≥ 32 weeks of gestational age and weighing $\geq 1500g$ who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis. • Provide care for infants convalescing after intensive care Provide mechanical ventilation for brief duration (< 24 hrs.) or continuous positive airway pressure or both. • Provide mechanical ventilation for brief duration (< 24 hrs.) or continuous positive airway pressure or both. • Stabilize infants born before 32 weeks of gestation and weighing < 1500g until transfer to a neonatal intensive care facility.

Effective Date: July 1, 2020
Meeting Date:

Form Locator 42
Page 9 of 59

<p>Level III NICU (c)</p>	<p>Level II capabilities plus:</p> <ul style="list-style-type: none"> • Provide sustained life support. • Provide comprehensive care for infants born < 32 weeks of gestational age and weighing < 1500g and born at all gestational aged and birth weights with critical illness. • Provide prompt and readily available access to a full range of pediatric medical subspecialists, and pediatric ophthalmologists. • Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide. • Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography.
<p>Level IV Regional NICU (d)</p>	<p>Level III capabilities plus:</p> <ul style="list-style-type: none"> • Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions. • Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site. • Facilitate transport and provide outreach education.

Health Care Provider Types

- (a) Pediatricians, family physicians, nurse practitioners and other advanced practice registered nurses.
- (b) Level I health care providers plus: Pediatric hospitalists, neonatologists and neonatal nurse practitioners.
- (c) Level II health care providers plus: Pediatric medical subspecialists, pediatric anesthesiologists pediatric surgeons, and pediatric ophthalmologists.
- (d) Level III health care providers plus: Pediatric surgical subspecialists.

South Dakota Department of Social Services (DSS), Division of Medical Services (Medicaid Agency) request for NUBC manual change for 837I transaction, Loop 2310F NMI situation rule

1. Brief description of requested action

The SD Medicaid Agency is requesting consideration for a change in the NUBC manual regarding 837I transactions, specifically the Loop 2310F situational rule. We are requesting that the manual indicate that either (a) the situational rule be modified to require the referring NPI on both outpatient and inpatient claims when the referring NPI is different than the attending NPI (currently is only required for outpatient claims); or (b) the situational rule be modified to include an additional statement that the referring NPI is required for inpatient claims when requested by the payor.

We are requesting this change for immediate effect.

2. Brief, non-technical description of the issue

Regarding the 837I transaction, Loop 2310F NMI, the X12 implementation guide has a situational rule delineating when the payee must include the referring provider NPI when different than the attending NPI. Specifically, with respect to the referring NPI, the situational rule states, "Required on an outpatient claim when the Referring Provider is different than the Attending Provider. If not required by this implementation guide, do not send."

The issue is that this situational rule omits inpatient claims. In order to effectively operate managed care and PCCM programs and to ensure proper FMAP, the health plan must be notified of the referring provider regardless of whether this is an outpatient or inpatient claim, and submission of this information is best suited and most efficiently submitted via the claim. In fact, in South Dakota, almost all providers and clearinghouses are providing the referring provider NPI for inpatient claims in Loop 2310F even though the situational rule prohibits it. Additionally, in an informal survey of Medicaid Agencies with PCCM and/or managed care programs, all responses indicated for inpatient claims they are requiring the referring provider when different than the attending provider, and most acknowledge they are requiring this information in Loop 2310F, as this is the logical mechanism in which the payee can provide this information to the Medicaid Agency. It should be noted that the paper claim, CMS 1450 (UB-04), does not restrict the referring provider name to only outpatient claims, but allows this information for both outpatient and inpatient claims. It is anticipated that for South Dakota alone, the FMAP budgetary impact of not receiving the referring provider name on inpatient claims could exceed \$20M annually.

3. Provide information regarding the “cause” of the proposed change

The CMS Office of Information Technology received a HIPAA transaction complaint from a clearinghouse payee that the South Dakota Medicaid Agency was improperly rejecting and denying inpatient claims because they were not including the referring NPI in Loop 2310F when the referring provider was different than the attending provider, in compliance with the X12 guidelines. We responded that we were not rejecting these 837I claims, but were denying payment after the 837I claims were imported into our adjudication system as not meeting the program requirements for a PCCM program. CMS found that we cannot deny payment when adjudicating a compliant 837I transaction with respect to the referring NPI.

As a result, we contacted the X12 workgroup and entered a request to modify the situational rule for Loop 2310F to either (a) modify the situational rule to require the referring NPI on both outpatient and inpatient claims (which would make it analogous with the CMS 1450 [UB-04] paper claim); or (b) modify the situational rule to include an additional statement that the referring NPI is required for inpatient claims when requested by the payor.

Our request to the X12 workgroup was rejected with the following statement:

“The work group reviewed your submission today and it has been rejected. This request would be a change for a future version of the Institutional 837 beyond 5010. We have been working on that next version which is 7030 and we believe your concern has already been addressed.

In 7030 the situational rule for the Referring Provider Loop ID 2310F has been changed to:

"Required when directed by the National Uniform Billing Committee (NUBC) Official UB Data Specifications Manual. If not required by this implementation guide, do not send."

Since the X12, version 7030, Loop 2310F situational rule has been changed to directly reference the NUBC manual, the X12 workgroup chair requested that we submit a request directly to the NUBC, and provided us a link to the NUBC webpage.

4. Explain what the change is intended to accomplish

Since, apparently, the X12, version 7030, 837I transaction, Loop 2310F situational rule is going to directly reference the NUBC manual, we are requesting a manual change to the situational rule as previously outlined in the response to #3. This change will accomplish four things:

1. It will make the 837I transaction analogous to the UB-04 paper claim as the UB-04 currently has no such referring NPI inpatient claim restriction;

2. It will provide an efficient mechanism to properly adjudicate and pay inpatient claims rather than devise other, work-around, mechanisms to obtain the referring NPI for inpatient claims when it is different than the attending provider. This creates fewer burdens on providers and clearinghouses, as well as health plans.
 3. It is our experience that, for South Dakota, all but one of the providers and clearinghouses that submit Medicaid claims to us “voluntarily” provide the referring provider NPI when different than the attending provider NPI on 837I transactions. This requested change will put them in compliance with the X12 guidelines and, by extension, the HIPAA transaction regulations. As previously noted, the current X12 guidelines actually prohibit a payee from submitting the referring NPI when different than the attending provider for inpatient claims. Through an informal survey of Medicaid Agencies with a PCCM or managed care program, for those that responded, all indicated that they are requiring the referring NPI when different than the attending NPI, and most acknowledged they are requiring this information in Loop 2310F.
 4. For inpatient claims, the referring NPI is necessary when it is different than the attending NPI in order to effectively operate managed care and PCCM programs, and to ensure proper FMAP. Without this information, it is anticipated that, for South Dakota alone, the FMAP budgetary impact could exceed \$20M annually.
5. Demonstrate that you are raising a national concern

As previously indicated, we feel there is a national concern in a few areas. First, as the situational rule relates to ensuring that payees are in compliance with the X12 guidelines, we believe there are a significant number of payees providing the referring NPI on the 837I Loop 2310F field when it is different than the attending provider, even though the situational rule prohibits this. This is likely due to Loop 2310F being the logical, preferred, and most common method of payees to report the referring NPI information to payors.

Second, to effectively operate a managed care or PCCM program and ensure proper FMAP, this referring NPI information is necessary and critical. Without it, there could be potentially huge FMAP fiscal impacts to the states.

Third, we believe there a great number of state Medicaid Agencies that are currently requiring the referring NPI for inpatient claims in Loop 2310F of the 837I when different than the attending provider. There could potentially be a number of HIPAA transaction CMS complaints nationwide as a result.

Finally, it makes no sense that the situational rule regarding the inpatient claims referring NPI be different than the requirements for completing a paper UB-04 claim.

We still have providers completing paper claims for which we can specifically require this referring NPI to effectively manage our PCCM programs and ensure proper FMAP, but cannot ask for this same information on an 837I.

6. Indicate whether the proposal was presented to the SUBC.

No, it was not.

7. Describe why existing UB-04 codes or alternative approaches are insufficient

See previous responses.

8. Indicate the impact on providers

As previously indicated, it is our experience that the majority of providers and clearinghouses are already providing the referring NPI for inpatient claims when it is different than the attending NPI in Loop 2310F. This is likely as it is logical to do so, because it is the most efficient and expeditious manner to provide this information and they want to be properly paid, and/or state Medicaid Agencies are actually requiring it in Loop 2310F. As such, we believe the impact to providers to be minimal.

However, if a state Medicaid Agency or health plan has created another mechanism for receiving this referring NPI information, we are proposing that the change to the NUBC manual for this situational rule optionally state that the referring NPI, when different than the attending NPI, only be required when requested by the payor. In this way, it would not necessitate programming changes for providers/clearinghouses that are providing the referring NPI through another state Medicaid Agency or health plan established mechanism.

9. Provide any further documentation that reinforces the national need for the proposed change

None except to reiterate that we believe the requested change to the manual for the Loop 2310F situational rule will advance positive impacts in the following ways:

- With no, or minimal impact, bring the majority of providers and clearinghouses into compliance since a significant number are currently submitting the referring NPI in Loop 2310F, even though the situational rule prohibits it.
- Ensure effective operations for PCCM and managed care operations.
- Ensure appropriate and proper FMAP dollars to state Medicaid Agencies.
- Bring many state Medicaid Agencies into HIPAA transaction compliance, and avert possible and potentially impactful and costly HIPAA transaction complaints to CMS.

- Avoid costly, non-efficient, and provider/clearinghouse and health plan burdensome alternative mechanisms to obtain the referring NPI for those inpatient claims.

NUBC CHANGE CONTROL REQUEST

(Return to Matt Klischer (mklischer@cms.hhs.gov) x 67488, N2-10-25)

DATE: July 11, 2019

REQUESTOR ORGANIZATION NAME: Division of Institutional Claims Processing (DICP), Provider Billing Group (PBG); Center for Medicare (CM), CMS

CONTACT PERSON: Fred Rooke

E-MAIL ADDRESS: fred.rooke@cms.hhs.gov

TELEPHONE NUMBER: 404-562-7205

PERSON(S) WHO WILL PRESENT THE CHANGE TO THE NUBC: Fred Rooke

DRAFT INSTRUCTION NUMBER (PLEASE ATTACH): A subset of requirements describing the use of these codes is attached.

DESCRIPTION OF ACTION REQUESTED (e.g. additional condition code needed):

Create two new condition codes to ensure bypass of matching of claim service locations to practice locations assignment on Hospital claims (see cause of change below):

Code	Short Descriptor	Long Descriptor
xx	Hospital Services Provided in mobile facility or with portable units	Enter this code to indicate that hospital services were provided in mobile facility or with portable units.
yy	Hospital Services Provided in patient's home	Enter this code to indicate that hospital services were provided in the patient's home.

CAUSE FOR CHANGE (regulatory, data collection, other): Regulatory – see Final rule published in Federal Register / Vol. 81, No. 219 / Tuesday, November 14, 2016, p. 79562.

A key component of the 2017 OPPS rule was the Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Certain Items and Services Furnished by Off-Campus Provider-Based Departments of a Hospital. The Final Rule, on p. 79701, says:

Historically, PBDs billed as part of the hospital and could not be distinguished from the main hospital or other PBDs within the claims data... While the modifier identifies that the service was provided in an off-campus PBD, it does not identify the type of off-campus PBD in which services were furnished, nor does it distinguish between multiple off-campus PBDs of the same hospital. As discussed in section X.A.2.e. of this final rule with comment period, in the CY 2017 OPSS/ASC proposed rule, we solicited public comments on the type of information that would be needed to identify non-excepted off-campus PBDs for purposes of section 603, although we did not propose to collect such information for CY 2017

Subsequently we implemented modifier PN and editing to match the service location from the claim records with the practice locations in the provider files populated from the 855A PECOS enrollment record. During the rulemaking process, commenters expressed concern about being dependent on the billing of other facility in order for institutional grouping to apply. Recently we received an inquiry from a provider that maintains portable mammogram unit services. Although we have been able to exclude certain claim services based on the service always being excluded from the service location to practice location matching (i.e. Ambulance services), we have been unable to perform the same exclusion for other services that may be rendered both at a hospital facility or by a mobile facility or with portable units or at a patient's home. To address these concerns, Medicare proposes the use of condition codes to allow the hospital to identify that a service was rendered by a mobile facility or with portable units or at a patient's home.

IMPACT STATEMENT (current form/instruction impacted, funding approved, implementation cost estimate, contractor operations impacted):

A change request for the April 2020 Medicare systems changes will be implemented in the April 2020 release. Costs and operations impacts will be assessed during the clearance process of that CR.

NOTE: Attach any documentation that clarifies this request, including documentation to support a request that is a result of a CMS mandate.

*******DO NOT COMPLETE THIS SECTION*******

Action Taken:

Final Disposition:

One-Time Notification

Pub. 100-20	Transmittal:	Date:	Change Request:
--------------------	---------------------	--------------	------------------------

SUBJECT: Updating FISS Editing for Practice Locations to bypass Mobile Facility and/or Portable Units and services rendered in the patient's home

EFFECTIVE DATE: April 1, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: April 6, 2020

I. GENERAL INFORMATION

A. Background: If a hospital claim is submitted with a service facility location that was not included on the CMS 855A enrollment form as a practice location, it will be Returned To the Provider (RTP'd) until the CMS 855A enrollment form and claims processing system is updated. However, there are exceptions to hospital claims where the service facility location will not be at a hospital owned location. Services rendered in a Mobile Facility and/or Portable Units and services rendered in the patient's home qualify as exceptions and should bypass the service facility location matching performed between the provider's claim and the providers practice location file. The National Uniform Billing committee has approved for usage two (2) new condition codes to identify claims where services were not provided at a provider's practice location.

B. Policy: No new policy.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC		D M E	Shared- System Maintainers				Other	
		A	B		H H H	M A C	F I S S	M C S		V M S
208616D.	The Shared System Maintainer shall update the reason					X				

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H	M A C	F I S S	M C S	V M S	C W F		
1	code "34978" to bypass Mobile Facility and/or Portable Units claims as identified with condition code "xx" and services rendered in the patient's home claims as identified with condition code "yy" with Dates of Service on or after January 1, 2017.										
208616D. 2	The Shared System Maintainer shall update the reason code "34977" to bypass Mobile Facility and/or Portable Units claims as identified with condition code "xx" and services rendered in the patient's home claims as identified with condition code "yy" with Dates of Service on or after November 2, 2015.					X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
208616D.3	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly.	X				

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
208616D.1 and .2	Condition codes xx and yy are placeholders for codes requested from the National Uniform Billing Committee (NUBC).

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Fred Rooke, fred.rooke@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the

part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Draft

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2323	Date: July 26, 2019
	Change Request 11268

SUBJECT: Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform the Medicare Administrative Contractors (MACs) that effective January 1, 2020, MACs should accept the Appropriate Use Criteria (AUC) related HCPCS modifiers on claims.

EFFECTIVE DATE: January 1, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 6, 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 2323	Date: July 26, 2019	Change Request: 11268
-------------	-------------------	---------------------	-----------------------

SUBJECT: Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging – Educational and Operations Testing Period - Claims Processing Requirements

EFFECTIVE DATE: January 1, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 6, 2020

I. GENERAL INFORMATION

A. Background: The Protecting Access to Medicare Act (PAMA) of 2014 section 218(b) established a new program to increase the rate of appropriate advanced diagnostic imaging services furnished to Medicare beneficiaries. Examples of advanced imaging services include computed tomography, positron emission tomography, nuclear medicine, and magnetic resonance imaging. Under this program, at the time an advanced imaging service is ordered for a Medicare beneficiary, the ordering professional will be required to consult a qualified clinical decision support mechanism (CDSM). A CDSM is an interactive, electronic tool for use by clinicians that communicates appropriate use criteria (AUC) information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition during the patient workup. There may be modules within or available through certified electronic health record (EHR) technology, private sector mechanisms independent from certified EHR technology, or those established by the CMS. The CDSM will provide the ordering professional with a determination of whether that order adheres to AUC, does not adhere to AUC, or if there is no AUC applicable (e.g., no AUC is available to address the patient's clinical condition) in the CDSM consulted.

Priority clinical areas are defined in 42 CFR 414.94(b) as clinical conditions, diseases or symptom complexes and associated advanced diagnostic imaging services identified by CMS through annual rulemaking and in consultation with stakeholders. Please note that AUC consultation is required for all advanced diagnostic imaging services, not just those within the priority clinical areas.

- Current Priority Clinical Areas
- Coronary artery disease (suspected or diagnosed)
- Suspected pulmonary embolism
- Headache (traumatic and non-traumatic)
- Hip pain
- Low back pain
- Shoulder pain (to include suspected rotator cuff injury)
- Cancer of the lung (primary or metastatic, suspected or diagnosed)
- Cervical or neck pain

When this program is fully implemented, a consultation must take place for any applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid under an applicable payment system. (Note the applicable setting is where the imaging service is furnished, not the setting where the imaging service is ordered.) Applicable settings include: physician offices, hospital

outpatient departments (including emergency departments), ambulatory surgical centers (ASCs), and independent diagnostic testing facilities. Applicable payment systems include: the physician fee schedule (PFS), the hospital outpatient prospective payment system, and ASCs.

Voluntary participation was established for this program from July 1, 2018 through January 1, 2020. CR 10481 discusses the voluntary participation period. This CR (11268) discusses the Educational and Operations Testing Period for calendar year (CY) 2020 (see additional information below).

Full program implementation is expected January 1, 2021. At that time, information regarding the ordering professional's consultation with CDSM, or exception to such consultation, must be appended to the furnishing professional's claim in order for that claim to be paid.

Exceptions to consulting CDSMs include: the ordering professional having a significant hardship exception, situations in which the patient has an emergency medical condition, or, an applicable imaging service ordered for an inpatient and for which payment is made under Part A.

Ultimately, PAMA requires that the program result in prior authorization for ordering professionals that are identified as having outlier ordering patterns. Before the prior authorization component of this program begins there will be notice and comment rulemaking to develop the outlier methodology.

B. Policy: Regulatory language for this program is in 42 CFR 414.94 titled Appropriate Use Criteria for Advanced Diagnostic Imaging Services. In the CY 2018 PFS final rule, CMS- said this program will be implemented in 2020 with an Educational and Operations Testing Period.

During this phase of the program claims will not be denied for failing to include AUC-related information or for misreporting AUC information on non-imaging claims (e.g., failure to include one of the below modifiers and/or one of the below G codes or reporting modifiers on the wrong line or wrong service), but inclusion is encouraged. In addition, the claims processing systems will be prepared by January 1, 2020, to accept claims that contain a Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) C code for advanced diagnostic imaging along with a line item HCPCS modifier to describe either the level of adherence to AUC or an exception to the program and a G-code to identify the qualified CDSM consulted.

During CY 2020 we expect ordering professionals to begin consulting qualified CDSMs and providing information to the furnishing practitioners and providers for reporting on their claims. Situations in which furnishing practitioners and providers do not receive AUC-related information from the ordering professional can be reported by modifier MH. Even though claims will not be denied during this Educational and Operations Testing Period inclusion is encouraged as it is important for CMS to track this information.

HCPCS modifiers have been established for this program for placement on the same line as the CPT code for the advanced diagnostic imaging service. These codes are available in the Attachment.

Claims that report HCPCS modifier ME, MF, or MG should additionally contain a G code to report which qualified CDSM was consulted. The G codes are available in the Attachment.

A subsequent CR will follow at a later date that will further operationalize this AUC policy.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C	Shared- System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
11268.1	Effective for claims with dates of service on or after January 1, 2020 and until further notice, contractors shall accept the AUC-related HCPCS modifiers on the same claim line as any Advance Diagnostic Imaging HCPCS code (see attachment 1).	X	X									IOCE
11268.1.1	Contractors shall accept claims with HCPCS modifier ME, MF or MG on the Advance Diagnostic Imaging service HCPCS code along with a separate line with a G-code from the attachment to report, which qualified CDSM was consulted.	X	X									
11268.2	Contractors shall follow normal current processes when dealing with new modifiers that are reported prior to their effective dates.	X	X									
11268.3	Effective for claims with dates of services on or after January 1, 2020, contractors shall accept the presence of the AUC-related G codes (see attachment 1) on claims. NOTE: Multiple G codes on a single claim is acceptable.	X	X									IOCE
11268.4	The G-codes in attachment 1 (codes that identify clinical decision support mechanisms) will be assigned a PFS procedure status indicator of "X" and will be assigned an Outpatient Prospective Payment System (OPPS) status indicator of "E1". Contractors shall apply a denial message for these line item G codes. These codes are not payable.	X	X									IOCE
11268.4.1	Contractors shall deny these G codes to ensure the information is carried through to National Claims History.	X	X									IOCE
11268.4.2	Contractors shall deny the G code line item with the following messages: MSN 36.7 This code is for informational/reporting purposes only. You should not be charged for this code. If there is a charge, you do not have to pay the amount. CARC 246 This non-payable code is for required reporting only RARC N620 Alert: This procedure code is for quality reporting/informational purposes only.	X	X									IOCE

Number	Requirement	Responsibility									
		A/B MAC		H H H	M A C	D M E	Shared-System Maintainers				Other
		A	B				F I S S	M C S	V M S	C W F	
	The Group Code is CO. NOTE: The beneficiary is not responsible for the denied charge.										
11268.5	Contractors shall refer to Attachment 1 for a list of HCPCS procedure codes that constitute advanced diagnostic imaging services subject to the Medicare appropriate use criteria program, HCPCS modifiers to be placed on the same line as any listed or unlisted procedure code and G codes for reporting the clinical decision support mechanism.	X	X								IOCE
11268.5.1	Contractors shall be notified of updates to Attachment 1 through the quarterly issuance of a Technical Direction letter.	X	X								IOCE

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility									
		A/B MAC		H H H	M A C	D M E	C E D I				
		A	B								
11268.6	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM11268.pdf	X	X								

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis Group) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis Group) , JoAnna Baldwin, 410-786-7205 or JoAnna.Baldwin@cms.hhs.gov (Coverage and Analysis Group).

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Attachment 1

Medicare Appropriate Use Criteria Program for Advanced Diagnostic Imaging – Code List

HCPCS Advanced Imaging Procedure Codes

Magnetic Resonance Imaging

70336, 70540, 70542, 70543, 70544, 70545, 70546, 70547, 70548, 70549, 70551, 70552, 70553, 70554, 70555, 71550, 71551, 71552, 71555, 72141, 72142, 72146, 72147, 72148, 72149, 72156, 72157, 72158, 72159, 72195, 72196, 72197, 72198, 73218, 73219, 73220, 73221, 73222, 73223, 73225, 73718, 73719, 73720, 73721, 73722, 73723, 73725, 74181, 74182, 74183, 74185, 75557, 75559, 75561, 75563, 75565, 76498, 77046, 77047, 77058, 77059,

Computerized Tomography

70450, 70460, 70470, 70480, 70481, 70482, 70486, 70487, 70488, 70490, 70491, 70492, 70496, 70498, 71250, 71260, 71270, 71275, 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, 72133, 72191, 72192, 72193, 72194, 73200, 73201, 73202, 73206, 73700, 73701, 73702, 73706, 74150, 74160, 74170, 74174, 74175, 74176, 74177, 74178, 74261, 74262, 74712, 74713, 75571, 75572, 75573, 75574, 75635, 76380, 76497

Single-Photon Emission Computed Tomography

76390

Nuclear Medicine

78012, 78013, 78014, 78015, 78016, 78018, 78020, 78070, 78071, 78072, 78075, 78099, 78102, 78103, 78104, 78110, 78111, 78120, 78121, 78122, 78130, 78135, 78140, 78185, 78191, 78195, 78199, 78201, 78202, 78205, 78206, 78215, 78216, 78226, 78227, 78230, 78231, 78232, 78258, 78261, 78262, 78264, 78265, 78266, 78267, 78268, 78270, 78271, 78272, 78278, 78282, 78290, 78291, 78299, 78300, 78305, 78306, 78315, 78320, 78350, 78351, 78399, 78414, 78428, 78445, 78451, 78452, 78453, 78454, 78456, 78457, 78458, 78459, 78466, 78468, 78469, 78472, 78473, 78481, 78483, 78491, 78492, 78494, 78496, 78499, 78579, 78580, 78582, 78597, 78598, 78599, 78600, 78601, 78605, 78606, 78607, 78608, 78609, 78610, 78630, 78635, 78645, 78647, 78650, 78660, 78699, 78700, 78701, 78707, 78708, 78709, 78710, 78725, 78730, 78740, 78761, 78799, 78800, 78801, 78802, 78803, 78804, 78805, 78806, 78807, 78811, 78812, 78813, 78814, 78815, 78816, 78999

C codes

C8900, C8901, C8902, C8903, C8905, C8908, C8909, C8910, C8911, C8912, C8913, C8914, C8918, C8919, C8920, C8931, C8932, C8933, C8934, C8935, C8936

HCPCS Modifiers

- MA Ordering professional is not required to consult a clinical decision support mechanism due to service being rendered to a patient with a suspected or confirmed emergency medical condition
- MB Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of insufficient internet access
- MC Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of electronic health record or clinical decision support mechanism vendor issues
- MD Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of extreme and uncontrollable circumstances
- ME The order for this service adheres to the appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- MF The order for this service does not adhere to the appropriate use criteria in the qualified clinical decision support mechanism consulted by the ordering professional
- MG The order for this service does not have appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- MH Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider

QQ Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional (effective date: 7/1/18)

G codes

- G1000 Clinical Decision Support Mechanism Applied Pathways, as defined by the Medicare Appropriate Use Criteria Program
- G1001 Clinical Decision Support Mechanism eviCore, as defined by the Medicare Appropriate Use Criteria Program
- G1002 Clinical Decision Support Mechanism MedCurrent, as defined by the Medicare Appropriate Use Criteria Program
- G1003 Clinical Decision Support Mechanism Medicalis, as defined by the Medicare Appropriate Use Criteria Program
- G1004 Clinical Decision Support Mechanism National Decision Support Company, as defined by the Medicare Appropriate Use Criteria Program
- G1005 Clinical Decision Support Mechanism National Imaging Associates, as defined by the Medicare Appropriate Use Criteria Program
- G1006 Clinical Decision Support Mechanism Test Appropriate, as defined by the Medicare Appropriate Use Criteria Program
- G1007 Clinical Decision Support Mechanism AIM Specialty Health, as defined by the Medicare Appropriate Use Criteria Program
- G1008 Clinical Decision Support Mechanism Cranberry Peak, as defined by the Medicare Appropriate Use Criteria Program
- G1009 Clinical Decision Support Mechanism Sage Health Management Solutions, as defined by the Medicare Appropriate Use Criteria Program
- G1010 Clinical Decision Support Mechanism Stanson, as defined by the Medicare Appropriate Use Criteria Program
- G1011 Clinical Decision Support Mechanism, qualified tool not otherwise specified, as defined by the Medicare Appropriate Use Criteria Program

Summary of NCVHS Visioning Session on Evaluating Standards for Adoption

The meeting was held 7/10 – 7/11/19 at the HHS building in DC.

The NCVHS participants were:

Alix Goss, Standards Subcommittee Co-chair, Imprado
Nick Coussoule, Standards Subcommittee Co-chair, BCBSTN
Bill Stead, NCVHS Chair, Vanderbilt
Rich Landen
Vickie Mays, UCLA
Denise Love, NAHDO
Deb Strickland, Conduent
Lorraine Doo, staff to Standards Subcommittee, CMS

The participants were:

ONC – Rob Anthony
Cooperative Exchange – Joe Bell
HATA – Chris Bruns
DSMO – Laurie Burckhardt
WEDI – Jay Eisenstock
Kaiser – Jamie Ferguson
HL7 – Chuck Jaffe
BCBSA – Gail Kocher
ADA – Jean Narcisi
NUBC – Todd Omundson
X12 – Cathy Sheppard
NUCC – Nancy Spector
NIST – Sheryl Taylor
MGMA – Rob Tennant
CAQH CORE – Erin Weber
NCPDP – Margaret Weiker
HIMSS – Rod Piechowski

The day started with a review of the work to date and recommendation to evaluate the function of the DSMO. A recap was given of the DSMO and its work. (See slides.) Points were made that:

- Today's discussion will frame work going forward
- Today's process does not work for evolving business needs as it lacks timely updates, manageable size of updates, testing of updates, etc
- HIPAA is 23 years old and business and the industry have changed
- A modern foundation for information exchange is needed to support future needs
- The merging of administrative and clinical data needs to be addressed

A toast of orange juice was done to symbolically congratulate the DSMO and its accomplishments.

The visioning session was moderated by a person with experience in conducting these types of visioning sessions.

The participants were grouped in five groups. Each group worked through the following exercises aimed at identifying a vision for a new “ecosystem” to evaluate standards for adoption.

Problem Statement

The group reviewed the problem statement, which is:

Barriers exist for the industry to adopt and implement updated versions of standards, implementation guides or operating rules on a predictable, reliable and timely basis sufficient to meet the evolving business needs of industry trading partners and their business associates.

The group voted individually on what they thought were the important aspects in the statement.

Stakeholders

The groups listed all of the stakeholders involved in the process and effected by the work.

Problem Tree Analysis

Each group completed a problem tree analysis identifying the causes and effects of problems in the current system.

How Might We Statements

Each participant created “how might we” statements and then each group came together on one statement.

All of the participants voted on one statement from the five presented. The statement with the most votes was:

How might we ... Implement new standards and technologies without regulatory interference while addressing appropriate priorities to better serve patients.

After discussion by the participants, the statement was updated to:

Align industry engagement to implement new standards and technologies that is synergistic with the regulatory process and is consistent, timely, and predictable to better serve patient priorities.

Importance Difficulty Matrix

On a flip chart, each group completed a matrix of identifying each step in the process and then prioritizing them from high to low. Each step was then organized by sequence. The result was four quadrants representing what tasks could be quick wins and longer-term work.

Concept Poster

Each group created a concept poster focused on one step of the ecosystem, including the name of the process and a diagram showing how it works.

On the second day, the NCVHS members completed a review of the concept posters by identifying what they liked, disliked, and thought missing in each. There was discussion about common themes across the posters.

Next Steps

The Subcommittee plans to:

- Take the work that has been done and synthesize it with feedback from the facilitator,
- Map out the various pieces, and
- Provide report out from their analysis.

They plan to present their work to the full committee at the October meeting.