National Government Services

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Medicare

ESA Teleconference Call - January 11, 2008

Introductory Remarks:

Effective July 30, 2007 CMS published a National Coverage Determination (NCD) for non-ESRD uses of erythropoiesis stimulating agents (ESAs) that would include future drugs of this class, as well as the current erythropoietin and darbepoetin. Also, as part of its LCD consolidation process, National Government Services, has revised its LCD (previously affecting only erythropoietin) for the ESA drugs. This was presented at the June 2007 Carrier Advisory Committee Meetings, and was finalized effective December 1, 2007. The LCD applies to all uses of ESAs.

The CMS NCD applied principally to the use of ESAs for anemia associated with malignancy and the treatments of the malignancy (chemotherapy or radiotherapy). The NCD covers ESAs administered for the anemia associated with chemotherapy used to treat non-myeloid malignancies, but not for an anemia associated with the malignancy, itself. Other uses of the drug, such as myelodysplastic syndrome or anemia of chronic disease, were left to the discretion of the individual Medicare contractors. National Government Services, through its LCD, has determined that ESAs should be covered for anemia associated with low grade myelodysplastic syndrome and specific chronic diseases.

National Government Services is aware that due to changes in the interpretation of the coverage and difficulties in creating and implementing appropriate processing system edits, claims for these drugs may have been incorrectly denied or inappropriately paid. Once the edits have been fully implemented, National Government Services will reopen claims to automatically adjust them. We apologize for any inconvenience and confusion that this has caused providers.

NOTE: Following the Ask the Contractor Teleconference, CMS Central Office was contacted to further clarify the starting dosage for epoetin. Although the NCD states that the starting dose is 150 units/kg three times weekly, or an equivalent dose given over other approved time periods, CMS has indicated that a starting dose of 40,000 units weekly (per the FDA-approved label) may be used even though this would exceed the calculated weight-based dose. Similarly, if darbepoetin is used the dose may be administered as 2.25µg/kg weekly, or 500 µg every three weeks, per the FDA-approved labeling. CMS has stated that "Clinically, it is probably appropriate to discontinue the ESA during the initiation period if the Hgb is above 10. The NCD just didn't require that. However, if a Hgb is performed and ESAs are given, then the most recent Hgb must be on the claim form and if above 10 the claim will be denied. The denial could be appealed and CMDs could choose to interpret the NCD to allow that payment." In the absence of any further instruction from CMS, National Government Services would uphold the denial. The hemoglobin/hematocrit should be repeated prior to the start of the maintenance period, and the continuation of the drug and dose based upon that result. During the maintenance period the hemoglobin/hematocrit may not exceed 10 g/dL or 30%. We have added an additional notation to those Q&A's addressing these issues.

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Also, subsequent to the Teleconference, CMS did publish CR #5699 with further instructions regarding the reporting of the most recent hematocrit or hemoglobin, and the use of the "EA", "EB" and "EC" modifiers. Hematocrit or hemoglobin test results are reported in the MEA03 segment Loop 2400 of the 837P or Item 19 of the CMS-1500 claim form. Information will be posted to the National Government Services Web site. See also *Medicare Claims Processing Manual* (pub. 100-4), Chapter 17, Section 80.

National Government Services did follow up on information that there were difficulties processing claims using the new modifiers. A system error in processing the J0885 with the "EC" modifier was identified and has been corrected.

QUESTIONS and ANSWERS:

Q1: In the new LCD, starting December 1, 2007, are we required to use the modifier "EJ"?
A1: No, the LCD no longer requires the use of the "EJ" modifier.

Q2: What are the new modifiers that are required for non-ESRD use of ESAs?
A2: There are three new modifiers available in HCPCS starting January 1, 2008. These are the "EA" (patient receiving chemotherapy for malignancy), "EB" (patient receiving radiotherapy for malignancy) and "EC" (patient receiving neither chemotherapy nor radiotherapy). [**Note (added during review): The effective date of these new modifiers is January 1, 2008 with an implementation date of (the date by which the Carrier must start using these rules for claims processing) April 7, 2008. See "Introductory Remarks" above].**

Q3: Is it necessary to include the patient's hemoglobin or hematocrit on the claim?
A3: Currently, CMS requires this information only on ESRD claims. It is anticipated that they will require it for all ESA claims, but they have not yet finalized any instructions to its contractors. **[Note (added during review): CMS issued a final Change Request #5699 after the Teleconference. See "Introductory Remarks" above].**

Q4: If we were to give a patient, as per the package insert, a 500µg dose of Aranesp® over three weeks, would that be over the cap?
A4: You would have to calculate the dose based upon the patient's weight (2.25µg/kg) and determine if the dose administered is within the dose set forth in the National Coverage Determination). [**Note (added during review): the dose may be administered as 2.25µg/kg weekly or as 500 µg every three weeks, per the FDA-approved labeling.]**

Q5: Is the diagnosis coding, with dual diagnoses, the same for the Aranesp® as it is for the Procrit®?
A5: Yes. The diagnosis coding reflects the patient's condition or diagnosis, independent of the specific drug used to treat the anemia. Note: the provider is required to submit three diagnoses (284.89, E930.7 or E933.1, and a diagnosis code for the specific malignancy) when administering ESAs to treat the anemia associated with chemotherapy.

Q6: Is lymphoma part of the non-myeloid malignancy family?
A6: Yes.

Q7: If we start a patient on Procrit® and switch to Aranesp®, would that be considered maintenance or initiation?
A7: Once the patient is started on an ESA, the administration of subsequent drug doses would be maintenance, even if changing to a different ESA or brand.

Q8: We had claims that were submitted with the new "E" modifiers and were denied. We were told (January 9) that the new modifiers are not in the system and to still use the "EJ" modifier.
A8: The new modifiers have been loaded into the claims processing system. We will check with claims processing systems to be sure that these modifiers are available and working correctly. (A contact number was provided by the caller for follow-up on the specific claims). **[Note (added in review): A system error in processing the J0885 with the "EC" modifier was identified and has been corrected.]**

Q9: Can a physician use 150µg/kg weekly for four weeks, during the initiation phase, and then switch to 500µg every three weeks on week five.
A9: The equivalent dose would be 450µg per week. [**Note (added during review): the dose may be administered as 2.25µg/kg weekly or as 500 µg every three weeks, per the FDA-approved labeling.]**

Q10: For the claims for ESAs that have been processed incorrectly, will the automated adjustments apply to Empire Medicare [National Government Services] or is that across the United States?
A10: The adjustments will be for National Government Services in New York and New Jersey. **[Note (added in review): Please monitor the National Government Services website for information and instructions concerning claims that may have been incorrectly denied].**

Q11: When claims are reopened for the automated adjustment, will Medicare be paying interest on these claims?
A11: No, CMS does not allow the interest payment on claims that have been processed timely, and are then reopened for adjustment. **[Note (added in review): Please monitor the National Government Services Web site for information and instructions concerning claims that may have been incorrectly denied].**

Q12: Is the GS for the first month that the hematocrit is over 39 and then does it go to "ED" for the second month and "EE" for the third? [Relates to claims from a dialysis unit being submitted to the Fiscal Intermediary].
A12: If the hematocrit has been greater than 39% for less than three months the "EE" modifier is required. If the hematocrit has been greater than 39% for more than three months then the "ED" modifier should be appended. The "GS" modifier should be used when the hematocrit has been greater than 39% and the dose of the ESA has already been reduced [by 25%]. The "GS" modifier should be used with the "ED" or "EE", whichever is appropriate**. [NOTE: initially, on the call, the descriptors of the "ED" and "EE" modifiers were transposed. The descriptors stated here are the correct ones].**

Q13: Effective January 1, 2008, do I need to populate value codes 49 and 68 (institutional billing) with the last hematocrit of the month and the total Epogen used for the month?

A13: We will have someone from the FI contact you with a response**. [Note (added during review): The value code 68 is no longer required after January 1, 2008. The value codes 48 [hemoglobin result] or 49 [hematocrit result] are required when HCPCS codes J0881, J0882, J0885, J0886 or Q4081 are reported (see CR #5699 final version, posted 1/11/2008)].**

Q14: If a patient's weight calculates out to an Aranesp® dose of 150ug per week, could the physician give them the 500ug once every three weeks and not waste the extra drug available in the vial?

A14: The physician could administer the 450ug and bill for the full 500ug vial, noting in the patient's medical record that the 50ug was discarded as wastage. [**Note (added during review): the dose may be administered as 2.25μg/kg weekly or as 500 μg every three weeks, per the FDA-approved labeling.]**

Q14a: …but it would not make sense to waste the drug, so could the physician administer the extra dose to the patient instead of wasting it?

A14a: This is a medical decision for the physician, based upon the safety of the administered dose. We will pay for the wastage that occurs with a vial. What is done with the extra amount is up to the physician and the medical needs of the patient, and potentially the medical risks to the patient.

Q15: A nephrology practice asked about the billing of ESA by NDC number on claims for dual-eligible beneficiaries (Medicare and Medicaid) [Medicaid requires the use of the NDC number].

A15: Medicare does not require the use of NDC numbers.

Q16: Is myelodysplastic syndrome (MDS) covered for low grade only, or can it be paid to treat anemia associated with higher grades of MDS?

A16: The anemia associated with MDS is covered only for low grade disease, coded by ICD-9 diagnosis code 238.72.

Q17: Since there has been difficulty in claims being paid when submitted using the diagnosis codes in the new LCD (effective December 1, 2007), should providers use the old LCD in order to expedite claims payment.

A17: No, providers should not use coding from the old (retired) LCD. These could lead to claims being denied not only during processing but also during any post-pay review. It is necessary for providers to continue to submit claims according to the current LCD based on date of service, and any claims that were incorrectly denied will be automatically reprocessed for adjustment.

Q18: For claims that were originally paid with 30 days and then reopened would interest be paid? For claims not paid within the 30-day period, would interest be paid?

A18: For claims that were paid timely, and then reopened, Medicare will not pay interest when reopened. For "clean" claims that are not paid timely, interest payments are made.

Q19: For a patient with chemotherapy-induced anemia, the LCD indicates that I need to code the malignancy, 284.89 and either E930.7 or E933.1. Do I also have to use a "V-code"?

A19: No, you do not use a "V-code." For chemotherapy-induced anemia, the only diagnosis codes that must be included on the claim are the 284.89, the E930.7 or E933.1, and a diagnosis code for the malignancy being treated.

Q20: When we started a patient on erythropoietin the hemoglobin was below 10, and we started at a dose of 40,000 units. If the patient's hemoglobin goes up one (1) g/dL we have to reduce the dose by 25%. When can we start the patient again at 40,000 units?

A20: If the hemoglobin jumps up 1 g/dL in the initial two weeks or subsequently goes above 10g/dL then the dose should be stopped. It can be restarted at 25% less if subsequently the hemoglobin falls below 10g/dL. [**Note (added during review): CMS has stated that "Clinically, it is probably appropriate to discontinue the ESA during the initiation period if the Hgb is above 10. The NCD just didn't require that. However, if a Hgb is performed and ESAs are given, then the most recent Hgb must be on the claim form and if above 10 the claim will be denied. The denial could be appealed and CMDs could choose to interpret the NCD to allow that payment." In the absence of any further instruction from CMS, National Government Services would uphold the denial. The hemoglobin/hematocrit should be repeated prior to the start of the maintenance period, and the continuation of the drug and dose based upon that result. During the maintenance period the hemoglobin/hematocrit may not exceed 10 g/dL or 30%].**

Q21: When we contact the call center to have claims reprocessed, we are being told that the new policy that is in effect, L25211, is retired and that the old policy L8897 is the effective policy.

A21: The effective policy is the L25211. We will contact the call centers to clarify the issues.

Q22: Regarding initiation of treatment: Are patients that have been on treatment on or before December 1, 2007 considered maintenance patients? Does this policy still affect them the same way?

A22: It affects them as maintenance. You do not have to reinitiate, and the policy affects them under the maintenance guideline. They must still meet all of the current guidelines, so that if they are receiving chemotherapy and their hemoglobin goes above 10g/dL then you have to stop the ESA, even if their therapy was initially started last July or May.

You do not have to repeat the qualifying tests. If you are treating a patient with MDS, it is not necessary to repeat their bone marrow test. You don't have to repeat their EPO levels.

Q23: In regard to the ICD-9 diagnosis code 285.29, last year we were billing for Procrit® with diagnoses of malaise and fatigue. This is no longer a covered code. Is that correct? Do we have to replace it with a new "E-code"?

A23: The diagnoses of malaise and fatigue are no longer covered diagnoses. The FDA labeling specifically indicates that these drugs are used to prevent transfusion and not just to treat the malaise and fatigue in these patients.

For patients with chronic disease there is a list of covered diagnoses: hepatitis, Crohn's disease or regional enteritis, or ulcerative colitis, lupus and rheumatoid arthritis. The hemoglobin or

hematocrit must still drop below 10g/dL or 30% respectively, to initiate therapy and the therapeutic range should not exceed a hemoglobin of 12g/dL or hematocrit of 36%.

Q24: Is the hemoglobin of 10g/dL or hematocrit of 30% strictly for chemotherapy associated with malignancy or is that for all diagnoses.

A24: The 10g/dL / 30% is for malignancy with chemotherapy. The others also have an initiation level of hemoglobin < 10g/dL or hematocrit < 30% but the maximum level instead of being a hemoglobin of 10g/dL, is 12g/dL **or 13g/dL for orthopedic cases**.

Q25: Are the "E" modifiers used for Part B only, and not Part A?

Q25: Although the "EA", "EB" and "EC" modifiers are listed in HCPCS, CMS has not yet provided instruction concerning their use. It is anticipated that instruction will be issued shortly, and providers should monitor the National Government Services website for further instruction. **[Note (added during review): The effective date of these new modifiers is January 1, 2008 with an implementation date of April 7, 2008, for Carriers and Fiscal Intermediaries. See "Introductory Remarks" above. Also, the modifiers "ED" and "EE" are used for ESRD claims].**

Q26: Are the requirements for hemoglobin/hematocrit levels (10/30) meant to be 10 or 30? *Either..or..?*

A26: Yes.

Q27: Is the reimbursable diagnosis for MDS (238.72) ever going to change in 2008?

A27: There is no current plan to change the diagnosis coding for MDS.

Q28: Does hemoglobin level need to be on the claim? I was under the impression that the hemoglobin level did not need to be on the claim.

A28: For ESRD patients the hemoglobin level is required. For non-ESRD patients that is not currently required, but this may change with new instructions that we are anticipating CMS to issue. **[Note (added during review): Subsequent to the Teleconference, CMS did publish CR #5699 with further instructions regarding the reporting of the most recent hematocrit or hemoglobin, and the use of the "EA", "EB" and "EC" modifiers. The effective date of these new modifiers is January 1, 2008 with an implementation date of April 7, 2008. See "Introductory Remarks" above].**

Q29: If a patient with renal failure but not on dialysis were started on EPO at 20,000 units and did not respond, would they be considered a non-responder and therefore would we be unable to increase the dose? Should we therefore start at a higher dose? We usually start at 40,000 units.

A29: The starting dose should be 150 units/kg three times a week. Once you have done that for four weeks, you can increase the dose by 25% at that time. [**NOTE: subsequent clarification was sought from CMS after the call. Providers may indeed initiate therapy with 40,000 units once a week per the FDA-approved package labeling, even though this may exceed the dose calculated at 150 units/kg tiw].**

Q30: Everything is being coded with two diagnosis codes except low grade myelodysplasia (238.72). This code can fly alone without an anemia code. Is that correct?

A30: This is correct, except that the anemia related to the treatment of a malignancy with chemotherapy requires three diagnosis codes (284.89, an E-code specific for the type of chemotherapy, and a diagnosis code identifying the malignancy).

Q31: If the patient is on multi-drug chemotherapy are we going to use the E933.1.

A31: The chemotherapy code would reflect that the chemotherapy drug is either an antibiotic type of chemotherapy drug or non-antibiotic type of chemotherapy drug.

Q32: When you contact the Call Center, providers were being told that there is the new policy #L25211 and the old policy #L8897, and that they can use both policies and that it depends which one fits. That's why they're denying some of the new chemotherapy codes or the malignancy codes that are in there. So, I think that at the Call Center it should be that #L8897 is not to be used now.

A32: This is correct. Only the LCD #L25211 should be referenced for dates of service on/after December 1, 2007. The LCD #L8897 should be used for dates of service prior to December 1, 2007.

Q33: If a patient has a low grade myelodysplastic syndrome with less than 5% blasts and an EPO level of less than 100, then you can use the code 273.2(?)? You don't need the anemia of chronic disease.

A33: For low grade myelodysplastic syndrome, the LCD requires only that the ICD-9 diagnosis code 238.72 be coded on the claim.

Q34: A patient who is two months post-chemotherapy with anemia and is now in renal failure, requires an ESA for treatment of his anemia. When does the coding for anemia secondary to chemotherapy end, and the coding for renal failure begin?

A34: The patient has a new diagnosis. If it is documented that the anemia is now related to the renal failure then that diagnosis should be used.

Q35: Do we need to indicate the hematocrit and the hemoglobin on claims for Aranesp® and Procrit®?

A35: Currently, the ESRD patients require the hematocrits. We are anticipating additional instructions from CMS that will clarify the inclusion of hematocrit and hemoglobin levels for non-ESRD patients. . [**Note (added during review): Subsequent to the Teleconference, CMS did publish CR #5699 with further instructions regarding the reporting of the most recent hematocrit or hemoglobin, and the use of the "EA", "EB" and "EC" modifiers. The effective date of these new modifiers is January 1, 2008 with an implementation date of April 7, 2008. See "Introductory Remarks" above].**

Q36: When a bone marrow test is performed, if the first attempt is a "dry tap" and a second attempt is made at a different site, do we use modifier "22" or modifier "50"?

A36: This is considered one service.

Q36a: Would this be modifier "22"?

A36a: The modifier "22" would probably not get paid because that would not be considered a significant increase of the service.

Q36b: But it's two bone marrow attempts – we're using two trays. It's two different sites. Would we use a modifier "59"?

A36b: This would have to be reviewed at the time when you submit the claim.
[Note (added in review): After reconsidering this question, we recommend that a bone marrow performed under the circumstances described should be submitted with a "22" modifier and then, with documentation, could be reviewed for additional reimbursement.]

Q37: For patients receiving Procrit® prior to surgery, the policy states that the patient must be evaluated to ensure that their anemia is due to chronic disease. Could you elaborate? Also could you elaborate on the ICD-9 diagnosis code V07.8?

A37: This means that it is necessary to be sure that the anemia is not due to a remedial cause, such as B12 deficiency, folate deficiency, or iron deficiency. It can only be used if the anemia is due to chronic disease. Also, it is not covered for non-anemic patients in anticipation of reducing transfusion requirements. The V07.8 (need for other specified prophylactic measure) diagnosis code is used because the EPO is administered to raise the hematocrit as a prophylactic measure for the surgery. The anemia of chronic disease code, 285.29, must be used and also the V07.8 code must be used.

Q37a: For the chronic disease you're not requiring that the patient have one of the chronic diseases that are listed in the anemia of chronic disease section?

A37a: That is correct, and this is only for patients undergoing orthopedic surgery.

Q38: Claims for patients with rheumatoid arthritis have been rejected. Can we assume that that's just because the new policy has not been loaded into the system yet?

A38: No, we are unable to make that determination on this call, as we have not seen the actual claim(s) to which you are referring. Please provide contact information so that we can discuss the claim with you directly.

Q39: For a patient with MDS who was started on Procrit® prior to December 1, if an EPO level was not done prior to December 1, do the new requirements require that a level be done after December 1?

A39: No, because the result of the test after the patient has been started on EPO is no longer valid. We would expect that they would have been done, but if they were not done, then we're not asking you to do them now.

Q40: On the initial starting level for Procrit® in a cancer patient, the only dosing strategies that are available is either the 150 units/kg three times a week or that combined into one time a week. Is that correct or are there other parameters?

A40: That is correct.

Q40: The 40,000 unit starting dose is not available any more?

A40: **[<u>NOTE</u> (added in review): subsequent clarification was sought from CMS after the call. Providers <u>may</u> indeed initiate therapy with 40,000 units once a week per the FDA-approved package labeling, even though this may exceed the dose calculated at 150 units/kg tiw].**

Q41: For a patient on Procrit® for cancer during that four week initiation period, if the hemoglobin or hematocrit goes above 10 g/dL or 30% respectively, then do we do a discontinuation until it drops below?

A41: **CMS has stated that "Clinically, it is probably appropriate to discontinue the ESA during the initiation period if the Hgb is above 10. The NCD just didn't require that. However, if a Hgb is performed and ESAs are given, then the most recent Hgb must be on the claim form and if above 10 the claim will be denied. The denial could be appealed and CMDs could choose to interpret the NCD to allow that payment." In the absence of any further instruction from CMS, National Government Services would uphold the denial. The hemoglobin/hematocrit should be repeated prior to the start of the maintenance period, and the continuation of the drug and dose based upon that result. During the maintenance period the hemoglobin/hematocrit may not exceed 10 g/dL or 30% [Note: The response to this question has been revised since the teleconference, based upon clarification from CMS].**

Also, only patients whose anemia is secondary to chemotherapy are covered for the ESA while on the drug, and for up to eight weeks after the completion. It is not covered for anemia due to cancer alone.

Q42: We do not generally check our patients with anemia of chronic diseases for their labs on a weekly basis, when they do them every week, every third week. With the new Medicare guidelines how would that work out for Medicare reimbursement?

A42: The way the NCD is structured, there is no specific requirement for specific time intervals. However, there are implied time intervals within the NCD for which we would expect lab tests would be drawn. These are at two weeks after initiation, four weeks after initiation and eight weeks after initiation. These are implied by the guidelines referencing the changes in hemoglobin and hematocrit at these points in time. Other intervals are left to the discretion of the physicians taking care of the patients and to their medical needs.

Q43: A caller revisited the issue of the "ED" and "EE" modifiers, pointing out that the descriptors had been transposed.

A43: We appreciate the caller's alertness and pointing out the error. As stated in Q12, above, the correct descriptors for the "EE" and "ED" modifiers are:

- Hematocrit more than 39% for **less** than 3 months……..use "EE" modifier
- Hematocrit more than 39% for **greater** than 3 months……use "ED" modifier.

Q44: Is the use of ESA drugs for orthopedic surgery limited to hip and knee surgery, or is it covered for any orthopedic surgery in which we expect a large blood loss?

A44: The policy is specific to just knee and hip surgery.

Q45: For Procrit®, if you can give 150 units/kg three times a week, then if administering the dose biweekly, can you give 900 units/kg biweekly, if the calculations for weight work out?

A45: Yes, you can use the cumulative dose of what the individual doses would be, qualified by the literature stating that the time interval that you've chosen is appropriate.

Q46: If 40,000 were not the starting dose, but I have a 175lb individual for whom the calculated dose

would be 34,000 units per week. Am I supposed to give him the 34,000 units and discard the 6,000 units remaining and document the wastage (the 40,000 units vial is not multi-dose use vial)?

A46: Medicare will pay for the wastage if you must discard part of the vial. What you give the patient must be medically necessary. Whether you administer the excess amount or discard is a medical judgment of what's best for the patient. [**NOTE: subsequent clarification was sought from CMS after the call. Providers <u>may</u> indeed initiate therapy with 40,000 units once a week, per the FDA-approved package labeling, even though this may exceed the dose calculated at 150 units/kg tiw].**

Q47: We've been facing a lot of denials for chemotherapy administration billed along with E/M. They have been denied as inclusive. To avoid this, how would you advise us to bill for payment?

A47: We will need to contact you directly if you are having trouble with these specific services.

Q48: As far as renal, I know that a second diagnosis is required. What would be the other diagnosis? Can that be fatigue and malaise?

A48: No. The LCD indicates that for anemia associated with renal disease, you need to code 285.21 (anemia of chronic kidney disease) and then a secondary diagnosis coding for the renal disease (e.g., 403.00-404, 585.3, 585.4 and 585.5).

Q49: We see a lot of patients with myeloid dysplasia. How old is the bone marrow report to still be sufficient? Is four or five years acceptable?

A49: If there were a previous bone marrow performed then it need not be repeated if it documents the presence of myelodysplasia. While a repeat marrow may be needed to evaluate the patient's condition, it is not required to be reimbursed for ESA administration. [**NOTE (added during review): If a subsequent marrow demonstrates that the MDS is no longer low grade, then the treatment of the MDS with ESA drugs may no longer be covered].**

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