EXETER HOSPITAL
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National Government Services Inc
Appeals Dept
8115 Knue Road
Indianapolis, IN 46250

March 05, 2024

Dear Sir or Madam,

This is a formal reconsideration request of LCD Article A52370 "Billing and Coding: Bevacizumab and Biosimilars".

Patients with the following conditions have had repeat hospitalizations and blood transfusions have been receiving successful treatment with Bevacizumab per multiple case studies, articles in peer reviewed journals, and the InHIBIT-Bleed study. These references are enclosed for further validation of this statement.

The conditions for consideration are: chronic refractory gastrointestinal (GI) bleeding secondary to hereditary hemorrhagic telangiectasia (HHT), arteriovenous malformations (AVM), and angiodysplasia of the stomach and duodenum with bleeding.

The compendia CMS affords have not considered GI bleeds related to these uncommon conditions.

Nationwide, Bevacizumab is being prescribed for patients with these conditions which has proven successful in controlling the bleeding and resulting anemia, need for transfusions and related hospitalizations. <u>These reductions in GI bleed admissions and blood transfusions is not only a cost savings but also an improvement in quality of life for these patients</u>.

This reconsideration request is being submitted to give these patients who have Medicare the same opportunity to receive this treatment without the need for an Advanced Beneficiary Notice (ABN). These notices often would cause patients to refuse this treatment regimen. There does not appear to exist any other coverage document in the form of an LCD, NCD, or within the regulatory manuals that we can find which then would lead us to provide an ABN because the drug "may" be denied and therefore indemnification is required under the Social Security Act 1879.

<u>AVMs in Hereditary Hemorrhagic Telangiectasia (HHT)</u>:

<u>Per the Mayo Clinic:</u> "Hereditary hemorrhagic telangiectasia is an inherited disorder that causes abnormal connections, called arteriovenous malformations (AVMs), to develop between arteries and veins. The most common locations affected are the nose, lungs, brain and liver.

These AVMs may enlarge over time and can bleed or rupture, sometimes causing catastrophic complications.

Spontaneous and unprovoked nosebleeds, sometimes on a daily basis, are the most common feature. Persistent bleeding from the nose and the intestinal tract can result in severe iron deficiency anemia and poor quality of life.

Also known as Osler-Weber-Rendu disease, hereditary hemorrhagic telangiectasia (HHT) is a genetic disorder that you inherit from your parents. Its severity can vary greatly from person to person, even within the same family."
https://www.mayoclinic.org/diseases-conditions/hht/symptoms-causes/syc-20351135#:~:text=Persistent%20bleeding%20from%20the%20nose,you%20inherit%20from%20your%20parents.

Micromedex already indicates appropriate Bevacizumab for HHT but focuses on "bleeding from the nose" versus the related AVM causing GI bleeds. These patients have severe iron deficiency anemia often requiring hospital admissions and blood transfusions. Currently, we have one patient with a vast history of multiple hospitalizations, blood transfusions and iron infusions with this condition that we can share should the panel want an example.

Therefore we offer the below diagnosis code as a proposed covered code for this treatment approach for patients with AVMs secondary to HHT.

ICD-10-CM Diagnosis Code I78.0
Hereditary hemorrhagic telangiectasia
Hereditary hemorrhagic telangiectasia syndrome; Osler hemorrhagic telangiectasia syndrome; Rendu-Osler-Weber disease

AVMs in digestive system vessels (without HHT):

AVMs (arteriovenous malformations) can be present without HHT. They can form anywhere in the body and can grow and change over time. There are 4 stages but not all AVMs go through all 4 stages. These stages are known as the Schobinger staging system. Gastric AVMs causing GI bleeds appear in professional literature as far back as 1976 in this JAMA Surgery article: https://jamanetwork.com/journals/jamasurgery/article-abstract/581501

Volumes of articles share information about AVMs appearing anywhere in the intestines, the duodenum, jejunum, as well as into the colon, with well-documented GI bleed concerns. Surgical interventions have had mixed outcomes, but treating with Bevacizumab for GI AVMs have shown great efficacy in controlling the bleeds, reducing blood transfusions and number of hospitalizations. This would directly create a large cost savings to Medicare by decreasing these occurrences. We have another patient with AVMs without HHT we can also offer as an example patient. We offer the below diagnosis code as a proposed covered code for this treatment approach for patients with this condition.

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ICD-10-CM Diagnosis Code 027.33

Arteriovenous malformation of digestive system vessel

Arteriovenous malformation of duodenum and jejunum; Arteriovenous malformation of intestinal vessels; Congenital arteriovenous malformation of the duodenum and jejunum; Congenital arteriovenous malformation of the gastrointestinal tract; Congenital duodenal and jejunal arteriovenous malformation (at birth)

Angiodysplasia of stomach and duodenum with bleeding

There is another less common condition that is being effectively treated with Bevacizumab nationally. In the enclosed referenced article: Intravenous Bevacizumab Reduces Transfusion Requirements And Endoscopic Interventions in Patients With Gastric Antral Vascular Ectasia And Small Bowel Angioectasia", complete cessation of bleeding episodes lasted for over a year. The need for blood transfusions and iron infusions were virtually eliminated.

We therefore offer the below diagnosis code as a proposed covered code for this treatment approach for patients with this condition.

ICD-10-CM Diagnosis Code K31.811

[convert to ICD-9-CM]

Angiodysplasia of stomach and duodenum with bleeding

- Gastric antral vascular ectasia w hemorrhage

Micromedex already considers Bevacizumab appropriate for HHT related AVMs in the nose, this request does not seem to fit the "off label" definition in LCD 33394: "Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication". Since the indication is the same (does not deviate significantly) but the site of the bleed differs (ICD-10-CM code not listed in LCD A52370) this lends to concern that the drug "may not be covered" and a requirement of an ABN.

The current LCD Article coverage is limited to Oncologic and Ophthalmic diagnoses.

We have included multiple articles from Gastroenterology Journals, Hematology Journals, and several PubMed articles taken from the NIH website expounding this treatment approach as well as its efficacy. We have been able to obtain commercial coverage for some of our patients post denial and review at appeal. We now seek to obtain a reconsideration that would allow for Medicare coverage for the above diagnoses. (We usually have the opposite in that we show Medicare coverage and then the commercial payers follow, this one is in reverse.)

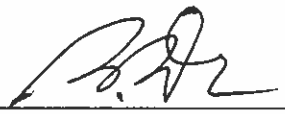
- We ask that you add the three diagnoses above to the covered diagnoses list within the existing LCD Article A52370 "Billing and Coding: Bevacizumab and Biosimilars" removing the scenario that the drug "may not be covered" and therefore the need for the ABN.

- We ask that the indications section be expanded to include coverage of AVMs of digestive system and gastric antral vascular ectasia with hemorrhage that have a history of bleeding that has required blood transfusions and iron infusions, or related endoscopy procedures, or related GI Bleed hospital admissions.

I kindly request that all contact and questions go through Sandra Egan. I have appointed her as my contact regarding this request. Her direct contact information is provided here. The aforementioned actual patient examples would be provided by her at your request:

Sandra Egan, RN, LNC
Phone: 603-580-7576
Email: segan@ehr.org

Respectfully submitted,



Bimalangshu Dey, MD Hematologist / Oncologist

Enclosures: Articles and studies supporting peer review and treatment for these conditions with this drug regimen. (V3767069, V3740720)