

CMS-1545-P-1 Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2008

Submitter : Mr. Scott Jones

Date & Time: 05/23/2007

Organization : Novartis Pharmaceuticals Corporation

Category : Drug Industry

Issue Areas/Comments

Consolidated Billing

Consolidated Billing

The Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities proposed rule for FY 2008, published in the Federal Register on May 4, 2007, invites comment on recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. 72 Fed. Reg. 25525, 25556 (May 4, 2007). As we explain below, an innovative and highly effective osteoporosis treatment called Reclast[®] (zoledronic acid) Injection satisfies those criteria, and requires separate payment to ensure that Medicare beneficiaries are afforded full access to its unique benefits.

CMS-1545-P-1-Attach-1.DOC



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May 23, 2007

BY ELECTRONIC DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8016

Re: CMS-1545-P; Consolidated Billing

Dear Sheila Lambowitz:

The Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities proposed rule for FY 2008, published in the Federal Register on May 4, 2007, invites comment on "*recent medical advances that might meet our criteria for exclusion from SNF consolidated billing.*"¹ As we explain below, an innovative and highly effective osteoporosis treatment called Reclast® (zoledronic acid) Injection satisfies those criteria and requires separate payment to ensure that Medicare beneficiaries are afforded full access to its unique benefits.

Impact of Osteoporosis on Medicare Beneficiaries

Bone fractures caused by osteoporosis exact an extraordinary and largely unrecognized human and financial toll. The Surgeon General warned recently in a special report on *Bone Health and Osteoporosis* that unless immediate action is taken by 2020 half of all Americans older than 50 will be at risk of fractures from osteoporosis and low bone mass. Today, 10 million Americans over the age of 50 have osteoporosis, while another 34 million are at risk of developing osteoporosis. Each year, about 1.5 million people suffer an osteoporotic bone fracture.

As the Surgeon General explained, hip fracture in particular frequently causes an elderly person's health to spiral downward. Twenty percent of elderly people who suffer a hip fracture end up in a nursing home within one year; and a hip fracture makes an elderly person four times more likely to die within three months. Hip fractures account for 300,000 hospitalizations each year.

Half of women over age 50 with osteoporosis will suffer an osteoporotic fracture within their lifetimes. Incidence of hip fracture in women is projected to rise 240% worldwide by 2050 as populations grow and age. The medical expense for treating broken bones from osteoporosis is as high as \$18 billion each year. The costs of long-term care and lost work add billions to this figure.

Background on Reclast

¹ 72 Fed. Reg. 25525, 25556 (May 4, 2007).

A new drug called Reclast®, currently being investigated by Novartis Pharmaceuticals Corporation (“Novartis”) for the treatment of postmenopausal osteoporosis, is the first once-yearly treatment that has been clinically proven to reduce significantly the incidence of bone fracture across the most common osteoporotic fracture sites. New Phase III data demonstrate that Reclast® is highly effective in reducing the incidence of hip and spine fracture—the most common fracture sites—in women with postmenopausal osteoporosis. The active ingredient in Reclast® is zoledronic acid. Reclast® belongs to a class of drugs called bisphosphonates and is administered via a once-yearly intravenous infusion.

A recent article in the *New England Journal of Medicine* concluded that patients treated with Reclast® remarkably experienced 70% fewer new spine fractures and 41% fewer hip fractures over a three year period than patients treated with placebo.² (A copy of this article is attached for your review.) The convenience of a once-yearly infusion will likely improve patient compliance over that of existing osteoporosis treatments. Moreover, over three quarters of study subjects preferred a yearly infusion over a weekly pill. Reclast® holds the potential to spare millions of elderly Americans premature death and disability and to save the health care system billions of dollars annually.

Reclast® was approved by the FDA in April 2007, to treat Paget’s disease. The PDUFA date for Reclast® concerning the treatment of Postmenopausal Osteoporosis is August 17, 2007.

Exclusion from Consolidated Billing

Under section 4432(b)(1) of the Balanced Budget Act of 1997 (BBA), the SNF consolidated billing provision applies to any beneficiary who “*is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility (as determined under regulations....)*” The Health Care Financing Administration (HCFA) interpreted this provision to “grant the Secretary the specific authority to define the concept of ‘services furnished to SNF residents’ further in regulations.”³ Pursuant to that authority, HCFA established that outpatient services, “*under commonly accepted standards of medical practice, lie exclusively within the purview of hospitals rather than SNFs, are not subject to Consolidated Billing, but are instead bundled to the hospital.*” Such services include “*cardiac catheterization, CT scans, magnetic resonance imaging, [and] ambulatory surgery involving the use of an operating room.*”⁴

The regulatory criteria for excluding specific services from the consolidated billing provision were further elaborated in the Balanced Budget Refinement Act of 1999 (BBRA). The BBRA targeted for exclusion “*high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment [SNFs] received under the prospective payment system.*”⁵

Reclast® Should be Paid Separately

Reclast® should be excluded from the SNF consolidated billing provision and paid separately under Medicare Part B. First, Reclast® will be a high-cost item. Although the final sales price for Reclast® has not yet been determined, it is likely to be considerably higher than a number of services that are already excluded from consolidated billing by statute or regulation, including CT, MRI, and

² Dennis M. Black, et al., “Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis,” 356 *New England Journal of Medicine* 1809 (May 3, 2007).

³ 63 Fed. Reg. 26298 (May 12, 1998).

⁴ *Id.* at 26298-99.

⁵ 72 Fed. Reg. at 25556 (citing BBRA Conference Report (H.R. Rep. No. 106-479 at 854) (1999)).

certain dialysis supplies and equipment. Second, by definition Reclast® is administered infrequently—specifically, one time per year.

Because of these factors, Reclast is especially susceptible to underutilization by SNFs. SNFs have strong incentive to use other, less expensive treatments for osteoporosis that are *theoretically* as effective in reducing the incidence of bone fracture, albeit for a much shorter period of time. As the clinical investigators for the Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly (HORIZON) Pivotal Fracture Trial recently reported in the *New England Journal of Medicine*, annual infusion of intravenous zoledronic acid achieved a 70% reduction in the vertebral fracture rate—far higher than the 40% to 50% reduction previously observed with weekly or monthly oral bisphosphonates. The investigators concluded that the greater effectiveness of once-yearly infusion was likely due to improved patient compliance:

A regimen of infusions once a year appears to ensure that patients will have a full treatment effect for at least 12 months. In contrast, many patients who receive prescription for oral bisphosphonates stop treatment, and most appear to be taking less than 80% of their prescribed pills by 12 months. Adherence to a regimen of oral bisphosphonates is challenging because the drug must be taken with a full glass of water when the patient is fasting, and the patient must remain upright for at least 30 minutes after taking the medication. Since poor adherence reduces the anti-fracture efficacy, a single annual infusion of zoledronic might improve such efficacy in clinical practice.⁶

Finally, because it is administered only once per year, there is no risk that excluding Reclast® from consolidated billing and paying it separately under Part B will encourage overutilization.

In order to ensure that Medicare beneficiaries who are residents of SNFs receive the benefits of this uniquely effective treatment for osteoporosis, it is therefore necessary to exclude Reclast from the SNF consolidated billing provision and to pay it separately under Part B.

Thank you for your attention to this important issue. We would welcome the opportunity to meet with you during the comment period to present additional clinical information on Reclast®.

Sincerely,

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Novartis Pharmaceuticals Corporation

⁶ Black, *supra* at 1818.

CMS-1545-P-2

**Medicare Program; Prospective Payment System and Consolidated
Billing for Skilled Nursing Facilities for FY 2008**

Submitter :

Date & Time: 06/07/2007

Organization :

Category : Other Health Care Professional

Issue Areas/Comments**Collection of Information**

Collection of Information

*We are attempting to use the TOY calculator to compare a few historic episodes. Our first road block is the availability of information in the CWF. The CWF (at least for us) shows the last two episodes. We need to see a history of episodes if we are to simulate retroactive responses for these historic episodes. Ongoing, we will need to be able to see up to four sequential episodes prior to our episode beginning.

*In order for us to better understand the impact of the proposed changes (and to our specific agency), it would be helpful if CMS would make available programming that would take our collective episodes in a specific time period (2006) and recalculate reimbursement using the proposed changes. If TOY is the answer to this, TOY needs programming changes since many of the TOY input fields result in inaccurate N/A response and then the totals do not add correctly and do not reconcile with the existing HHRG code. If there are errors with the existing HHRG calculation, how do we know the proposed new HHRG calculations are correct?

GENERAL

GENERAL

* In regard to the Early/Late designation of the episode, CMS should give the agencies the ability to look up four sequential episodes prior to the episode in question in order to complete the Oasis properly. CMS should automatically correct this answer (both favorably or unfavorably as it relates to reimbursement) as needed with updated information in the CMS system.

* Will the regulations be changed to only require Oasis be submitted for the calculation of the HHRG? For example, why would a follow up Oasis be required if the follow up Oasis is not factoring into the reimbursement (as it currently may be)?

*

Impact Analysis

Impact Analysis

* If 2003 Medicare claims are the latest Medicare claims available for use in this proposal, I think the information is too old and should be updated. Surely CMS should have access to Medicare claims through 2006 or worse case 2005. I wouldn't think the 2003 information would give good comparisons to the financial impact the proposed changes would have on agencies today.