From:	Murphy, Barb
To:	Medicare Policy Comments
Subject:	LCD Reconsideration Request LCD L34648 Bisphosphonate Drug therapy and Coverage Article A56907 Bisphosphonate Drug Therapy
Date:	Monday, May 16, 2022 5:17:43 PM
Attachments:	image001.png UpToDate Prevention and treatment of glucocorticoid-induced osteoporosis 3.22.pdf UpToDate Osteoporosis after solid organ or stem cell transplantation eff 3.22.pdf ASCO Use of Adjuvant Bisphosphonates and Other Bone-Modifying Agents in Breast Cancer_ ASCO-OH (CCO) Guideline Update 1.2022.pdf NCCN Guidelines Breast Cancer MS39 adjuvant use of bone agents.pdf Denosumab cessation Cleveland Clinic June 2020.pdf Fracture Risk and Mgmt discontinuation denosumab therapy JCEM 2021.pdf Increased Risk of Multiple Spontaneous Vertebral Fractures at Denosumab Discontinuation Must Be Taken Into Account ASCO 3.2020.pdf NCCN zoledronic acid Prostate cancer.docx

You don't often get email from murphyb@wustl.edu. Learn why this is important

WARNING: This is an external email that originated outside of the WPS email system. DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe!

Hello:
This is a reconsideration request regarding LCD #L34648 Bisphosphonate Drug Therapy and Coverage Article: Billing and Coding: Bisphosphonate Drug Therapy (A56907)

These services fall under section 50 Drugs and Biologicals benefit category of the CMS IOM, Medicare Benefit Policy Manual Chapter 15.

There are additional indications that are standard of care for these agents which are not included in this LCD, or coverage article. There are additional indications and diagnosis codes which are supported in current literature and Clinical Oncology resources.

I will begin with **four additional indications:**

1. **Treatment/prevention of glucocorticosteroid induced bone loss. And post-transplant bone loss due to glucocorticosteroids, cyclosporine and tacrolimus.** This indication is supported by numerous professional societies and listed in Up to Date Current articles. This indication is included in the Medical policies of other plans including another Medicare Carrier. Some of these are:
    a. First Coast LCDL33270 Coverage Article A57603
    b. Aetna Commercial
    c. First Cigna
    d. Federal Blue Cross Blue Shield
    e. United Healthcare Commercial

    Additional support documents for these indications (attached)
    - *UpToDate Osteoporosis after solid organ or stem cell transplant*
    - *UpToDate Prevention and treatment of glucocorticoid-induced osteoporosis*

    Suggest accepting ICD10 diagnosis codes
    Z79.52 long term (current) use of systemic steroids + M85.80-M85.9 other specified disorder of bone density and structure or M89.9 bone disorder unspecified
    In the post-transplant setting: long term steroid code; or for cyclosporine or tacrolimus the diagnosis code Z79.899 other long term (current) drug therapy +/- one of the transplant status codes Z94.0-Z94.9

2. **<u>Adjuvant treatment to reduce the risk of bone recurrence in post- menopausal patients with breast cancer</u>**

   Supporting documents (attached*):*
   - *American Society of Clinical Oncology (ASCO) Guidelines 1.2022*
   - *NCCN Guidelines Breast Cancer MS39*

   For coding guidance suggest either the Breast cancer diagnosis code (C50.01-C50.929), lobular carcinoma in situ of breast (D05.00-D05.02) ductal carcinoma in-situ (D05.10-D05.12) other specified type of carcinoma in situ of breast (D05.80-D05.82), personal history breast cancer (Z85.3) or personal history of in- situ neoplasm of breast (Z86.000) (Keeping in mind that many times patients with in situ breast cancer are treated with hormonal therapy.)

3. **<u>Treatment with zoledronic acid when completing therapy with Prolia/Xgeva (denosumab)</u>** (all indications) When a patient has been on Prolia/Xgeva (denosumab) therapy for a period of time, studies indicate that when this therapy is discontinued, there is an increased risk of spontaneous vertebral fractures /rapid loss of bone mineral density gains during the denosumab therapy. In these situations clinical guidance recommends one-two doses (at 6 month intervals) of zoledronic acid to mitigate this loss. The diagnosis code requirements currently in the bisphosphonates coverage article would not support this indication. The ICD10 diagnosis code, Z79.811 long term (current) use of aromatase inhibitor, would not be used because the language of the diagnosis code states "(current)". These patients typically are no longer taking AI's
   Possible diagnosis codes to use would be Z92.241 personal history of systemic steroid therapy or Z85.29 personal history of other drug therapy.
   Supporting documents (attached):
   - *Denosumab Cessation Cleveland clinic June 2020*
   - *Fracture Risk and Management of Discontinuation of Denosumab Therapy: A Systematic Review and Position Statement by ECTS October 2020*
   - *Increased Risk of Multiple spontaneous vertebral fractures at Denosumab Discontinuation must be taken into Account Editorial Journal of clinical Oncology ASCO March 2020*

4. **<u>Treatment of bone loss in men receiving androgen deprivation therapy for metastatic prostate cancer or simply remove "non-metastatic" from the indication.</u>**
   The current NCCN compendium and guidelines do not limit this therapy to non-metastatic prostate cancer patients. There is an indication: *Prevention or treatment of osteoporosis during androgen deprivation therapy (ADT) for patients with high fracture risk.* Treatment of metastatic prostate cancer with androgen deprivation therapy is standard of care. Therefore risk of bone loss is not limited to non-metastatic prostate cancer patients.
   Along with this proposed additional indication, I propose acceptance of the Prostate cancer diagnosis code C61 or Z85.46 personal history of prostate cancer to cover this therapy.
   Supporting Documents (attached)
   - *NCCN Guidelines/compendium Zoledronic acid Prostate Cancer (snip)*

In addition to these four additional indications, I have the following **suggestions for ICD10 diagnosis code** additions for indication already listed in the policy.

1. **<u>Treatment of bone loss in woman receiving adjuvant aromatase inhibitor therapy for breast cancer:</u>**
   For coding guidance suggest either the Breast cancer diagnosis code (C50.01-C50.929), lobular carcinoma in situ of breast (D05.00-D05.02) ductal carcinoma in-situ (D05.10-D05.12) other specified type of carcinoma in situ of breast (D05.80-D05.82), personal history breast cancer (Z85.3) or personal history of in- situ neoplasm of breast (Z86.000) Keeping in mind that many times patients with in situ breast cancer are treated with hormonal therapy. The NCCN Compendium lists the breast cancer diagnosis codes. I am in the process of requesting they add the other codes above also.
   Given the history of requiring three diagnosis codes, I propose that the above codes be allowed interchangeably with the currently required Z85.3. Many patients with active breast cancer and in situ breast cancers are treated with aromatase inhibitors. Only allowing Z85.3 personal history of breast cancer prevents the compliant coding of these patients.

2. **<u>Treatment of bone loss in men receiving androgen deprivation therapy</u>** diagnosis coding

suggestions are in #4 above.

We thank you for your consideration of these items on behalf of the Division of Oncology at Washington University School of Medicine and also on behalf of a patient population for whom we have had difficulty providing medically necessary care due to these policies.

Should you wish to discuss, please feel welcome to connect with me.

Kind Regards,

Barbara K Murphy, CPC
Manager, Coding Compliance
Division of Oncology

Mid Campus Center Suite 11500
4590 Children's Place
St Louis, MO 63110
T: 314.362.0163 E: murphyb@wustl.edu

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.