

Provider Update

Volume 27, Issue 5

September/October 2010

LaHIPP Program Partners with Health Management Systems

Effective March 1, 2010, Health Management Systems (HMS) assumed the administrative and operational duties of the Louisiana Health Insurance Premium Payment (LaHIPP) Program.

The Department of Health and Hospitals has partnered with HMS to grow the LaHIPP Program while maintaining a strong focus on customer service to existing clientele. HMS has brought innovation to the LaHIPP program by developing an online application which can be accessed via the LaHIPP website. HMS has also taken a proactive approach towards outreach with Medicaid enrollees through mailers and telephone calls using predictive dialer software. Outreach to the Medicaid provider community is being made through in-service visits and the development of LaHIPP informational packets.

The LaHIPP Program reimburses some or all of the health insurance premiums for qualifying clients. To qualify for the LaHIPP program, individuals must have access to employer sponsored insurance (ESI), have a dependent that is certified to receive Medicaid and is enrolled in the ESI, and have their case determined as cost effective. In addition to assistance with paying health insurance premiums, LaHIPP pays for the out of pocket expenses for the LaHIPP certified Medicaid enrollees who are active in the ESI. Currently, LaHIPP is assisting over 1000 policyholders with their health insurance premiums.

For more information, visit the LaHIPP website at <http://www.dhh.louisiana.gov/offices/?ID=148> or call the LaHIPP team at 1-888-My-LaHIP (888-695-2447).

Table of Contents

<i>LaHIPP Program Partners with Health Management Systems</i>	1	<i>Changes in the Long Term - Personal Care Services Program</i>	3
<i>Medicaid Professional Services Program Coverage of '17P'</i>	2	<i>Avoid Hiring or Employing Excluded Individuals</i>	4
<i>Radiology Utilization Management Update</i>	2	<i>Remittance Advice Corner</i>	5
<i>New Service for the Elderly and Disabled Adult Waiver Program</i>	3	<i>Online Medicaid Provider Manual Chapters</i>	10
		<i>Pharmacological Management of Postmenopausal Osteoporosis</i>	11

Professional Services Providers

Medicaid Professional Services Program Coverage of '17P'

Effective with date of service September 1, 2010, the Louisiana Medicaid Professional Services program now covers weekly intramuscular injections of 17 Alpha-Hydroxyprogesterone Caproate (17P) for pregnant women with a history of pre-term delivery before 37 weeks and no current pre-term labor symptoms. Detailed policy information regarding patient criteria, medication use and provider billing requirements is available on www.lamedicaid.com by following the links of Training/Policy Updates, Provider Training Packets/Policy Updates, 2010 Provider Training/Policy Updates, and Professional Services Program.

Questions regarding the use and billing of 17P should be directed to Molina Medicaid Solutions Provider Relations at (225) 924-5040 or (800) 473-2783.

Professional Services and Radiology Providers

Radiology Utilization Management Update

Earlier this year, Medicaid partnered with MedSolutions, Inc. (MSI) to implement the Radiology Utilization Management (RUM) program to ensure the appropriate utilization of specified high-tech imaging studies. During the implementation phase of this program, several issues were identified which resulted in some procedural changes for providers. Information about these changes can be found in the June 7, 2010 provider notice which is available at www.lamedicaid.com following the "Radiology Util Mgmt" link.

Providers are reminded to have procedures in place to request authorizations prior to the delivery of services, to review authorizations to confirm services have been approved and assigned to the correct rendering facility and to make changes in a timely manner. Requests for a retroactive review after the performance of a procedure should only be made when unavoidable circumstances occur. Requests that are determined as not medically necessary will be denied.

Providers should monitor the LA Medicaid website on a regular basis for notices regarding policy clarifications or program changes. Questions concerning authorization or assistance with requests should be directed to MSI at (888) 693-3211 or www.medsolutionsonline.com. Questions concerning billing issues should be directed to Molina Provider Relations at (800) 473-2783 or (225) 924-5040.

Elderly and Disabled Adult Waiver Providers

New Service for the Elderly and Disabled Adult Waiver Program

Effective July 4, 2010, the Elderly and Disabled Adult (EDA) Waiver began offering a new service to its recipients, EDA Personal Assistance Service (PAS). In the past, EDA Companion Service and Long Term - Personal Care Service were utilized for waiver recipients who required assistance with supervision and their personal care needs. Recipients can now receive this type of assistance through a single waiver service.

The May 2007 policy on Waiver - Hospice Concurrent Care is still applicable for coordination of hospice and waiver services and does not change with the replacement of EDA Companion Service with PAS. A copy of the waiver - hospice policy is available on the website at

<http://www.dhh.louisiana.gov/offices/publications.asp?ID=105&Detail=3215>.

Additional information regarding EDA PAS covered tasks, billing codes, rates, and service documentation is available on the Office of Aging and Adult Services' website at

<http://www.dhh.louisiana.gov/offices/publications.asp?ID=105&Detail=3124>.

Long-Term Personal Care Service Providers

Changes in the Long Term - Personal Care Services Program

Changes to the Long Term-Personal Care Services (LT-PCS) Program were implemented September 5, 2010 due to the emergency rule that was published in the *Louisiana Register* on August 20, 2010. Changes to the LT-PCS program include a reduction of the maximum service hours from 42 to 32 hours per week and the implementation of a simplified assessment and care planning process. A notice was mailed to each LT-PCS recipient on August 19, 2010 regarding these changes. A copy of this notice can be viewed on the website of the Office of Aging and Adult Services at

<http://www.dhh.louisiana.gov/offices/publications.asp?ID=105&Detail=3214>.

This emergency rule also provided clarification on:

- Provisions governing restrictions of the paid direct service worker,
- Provisions governing restrictions for the place of service,
- Provisions of who can be designated as the recipient's responsible representative, and
- Requirements for a direct service worker's certification in cardiopulmonary resuscitation and first aid.

The emergency rule can be viewed in its entirety on the website of the Louisiana Office of the State Register at <http://www.doa.louisiana.gov/osr/reg/1008/1008.pdf>.

All Providers

Avoid Hiring or Employing Excluded Individuals

As a condition of participation in the Louisiana Medicaid Program, providers are responsible for ensuring that current as well as potential employees and/or contractors have not been excluded from participation in the Medicaid or Medicare Program by Louisiana Medicaid and/or the Office of Inspector General (OIG). Providers who employ or contract with excluded individuals or entities may be subject to penalties of \$10,000 for each item or service the excluded individual or entity furnished.

Providers should check the following two websites prior to hiring or contracting with an individual or entity and should routinely check the websites for determining the exclusion status of current employees and contractors. All current and previous names used such as first, middle, maiden, married or hyphenated names and aliases for **all owners, employees and contractors** should be checked.

- <http://exclusions.oig.hhs.gov/search.aspx>
- <http://www.epls.gov/eplsearch.do>

If an individual's or entity's name appears on either website, this person or entity is considered excluded and is barred from working with Medicare and/or the Louisiana Medicaid program in any capacity. The provider must notify the Department of Health and Hospitals with the following information:

- Name of the excluded individual or entity and
- Status of the individual or entity (applicant or employee/contractor).

If the individual or entity was an employee, the provider should also include the following information:

- Beginning and ending dates of the individual's or entity's employment or contract with the agency,
- Documentation of termination of employment or contract, and
- Type of service(s) provided by the excluded individual or entity.

These findings should be reported to:

Department of Health and Hospitals
Program Integrity - Special Investigations Unit
P. O. Box 91030
Baton Rouge, LA 70821-9030
Fax: (225) 219-4155

Medicaid providers should review the information provided in the SPECIAL ADVISORY BULLETIN titled "The Effect of Exclusion from Participation in Federal Healthcare Programs" at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>.

Sections E, F, and G of the bulletin explain the prohibition against hiring excluded individuals or entities and the fines and penalties involved when an excluded individual or entity is hired or contracted.

All Providers

Remittance Advice Corner

The following is a compilation of messages that were recently transmitted to providers through Remittance Advices (RA):

Laboratory, Radiology, and ASC (Non-Hospital) Providers: Implementation of Aug 2010 Reimbursement Rate Reductions

The reimbursement rate reductions effective with dates of service on or after August 1, 2010 for laboratory, radiology, and ASC (Non-Hospital) have been loaded in the system. Providers should reference the "Fee Schedules" link on the homepage of the LA Medicaid website (www.lamedicaid.com) for the most current fees. These rate reductions began appearing on the RA of August 10, 2010. A systematic adjustment of claims will be unnecessary due to timely implementation. Contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions concerning the rate reductions.

Professional Services and KIDMED Providers Implementation of January 2010 Rate Reductions

The reimbursement rate reductions for professional services effective with date of service January 22, 2010 have been implemented. Providers began seeing these reductions on the RA of July 20, 2010. Refer to the Office for the State Register's website at <http://doa.louisiana.gov/osr> for published rules detailing these reductions. Providers should monitor the LA Medicaid website (www.lamedicaid.com) for updates to the Professional Services Fee Schedule to occur in the near future. A supplement to the fee schedule will also be posted detailing the procedure codes affected by the reductions. Continue to monitor future RAs for details regarding when the recycle of these claims will take place. Contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions related to the implementation of the rate reductions.

Rehab Centers, Ambulance Transportation, KIDMED Screening Clinics, DME, Mobile X-ray/Radiation Therapy Centers & Optical Suppliers

As detailed in the Remittance Advice (RA) published in June/July 2010, there are claims that were reimbursed referencing the wrong fee on the file on the RAs of 5/25/10, 6/1/10, 6/8/10 and 6/15/10. The fees and programming logic were updated and claims that were previously reimbursed erroneously will be systematically adjusted on the RA of 8/10/10. No action is required by providers. A detailed list of the codes impacted has been posted on www.lamedicaid.com. Please contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions concerning the error and adjustment of claims.

All Providers

Update on "ClaimCheck" Denials Related to Modifier 51

The resolution to the modifier 51 issue necessitating that providers delay the resubmission of claims that received "ClaimCheck" denials for errors 934 (Modifier 51 Required-ClaimCheck) and 938 (Modifier 51 Invalid-ClaimCheck) is close to completion. Testing of this update to the claims processing system is currently in progress and it is anticipated it will be complete in the next few weeks. To expedite proper payment for providers, when the update is complete, claims denied for these errors will be recycled. Providers will not need to take any action. Providers will be notified when the update is complete and provided with details of the recycle via notices on the Louisiana Medicaid website homepage at www.lamedicaid.com, under the "ClaimCheck" icon on the website, as well as on their RA messages. For further questions related to this matter, please contact Molina Provider Relations at (800) 473-2783 or (225) 924-5040.

Professional Services Providers

Update to Precertification Policy Related to Inpatient Physician Claims

Effective with date of service August 30, 2010, in conjunction with the updates to the precertification/length of stay criteria for all acute hospital stays, the claims processing edits were updated related to physicians' inpatient services. Physician inpatient services will continue to be edited to assure that the inpatient hospitalization has been precertified/approved. When there is no approved precertification on file, the inpatient physician services will deny. For a description of exceptions related physician charges when hospital stays are not precertified, refer to the *2007 Professional Services Training* manual, page 76. For further questions related to this matter, please contact Molina Provider Relations at (800) 473-2783 or (225) 924-5040.

Implementation of January 2010 Physician Administered Drugs Rate Adjustments

The reimbursement rate adjustments for physician administered drugs effective with date of service January 22, 2010 have been implemented. Providers will begin seeing these reductions on the RA of August 17, 2010. Refer to the Office of the State Register's website at <http://doa.louisiana.gov/osr> for published rules detailing these reductions. Providers should visit the LA Medicaid website (www.lamedicaid.com) for updates to the Professional Services Fee Schedule. The adjustment of claims for physician administered drugs paid between January 22, 2010-August 17, 2010 will be included in the upcoming adjustment of professional services claims for the August 2009 and January 2010 rate reductions. There is still a delay in implementing these adjustments as we assess available options for providers. Continue to monitor future RAs for details regarding when the recycle of these claims will take place. Contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions related to the implementation of the rate reductions.

All Providers

Hospital Providers and Physician Providers: Precertification Changes

Effective August 30, 2010, two significant changes were made concerning hospital policy and precertification requirements:

1. Change in policy for the outpatient 24 hour rule, and
2. Change in requirement for hospital precertification of deliveries and accompanying billing changes.

Please visit www.lamedicaid.com and click on the "Acute Precert" link for detailed provider notices concerning these changes.

All Providers: Change in Paper Remittance Advices

Effective August 24, 2010, two changes were made to the LA Medicaid paper remittance advice (RA). The following changes were made to address recent concerns raised by providers:

- A change was made to display a "NET" amount for Adjustment/Previously Paid claims. The "NET" amount is the calculated difference between the Previously Paid amount and the Adjusted amount. The "NET" amount will display below the payment in the Adjustment section of the RA. If the NET adjusted amount is less than the original payment, a minus (-) sign will display after the difference posted. This is intended to help address provider's concerns with reconciling their RA when adjustments are made as a result of rate reductions.
- The procedure description has been shortened to accommodate displaying up to 4 modifiers on the RA. In circumstances where it is necessary to use multiple modifiers, all modifiers will appear on the RA with the procedure code.

Should you have questions concerning this change, please contact Provider Relations at (800) 473-2783 or (225) 924-5040.

Hospital Providers: Implementation of August 1, 2010 Rate Reductions

The August 1, 2010 rate reductions for inpatient and outpatient hospital services were implemented. Providers began seeing these reductions on their remittance advices beginning August 31, 2010. Claims for dates of service after August 1, 2010 that were already adjudicated were systematically adjusted on the remittance advice dated September 7, 2010 and no action was required by providers. The exception to this was if an inpatient stay spanned the August 1, 2010 date, these claims would have to be voided and split-billed in order to be paid correctly. Any questions should be directed to Provider Relations at (800) 473-2783 or (225) 924-5040.

All Providers

Attention Free Standing ESRD Facilities: Delayed Implementation of Aug 2010 Rate Reductions

Effective with dates of service on or after August 1, 2010, the reimbursement rates for Free Standing ESRD Facilities are further reduced by 4.6%. For details regarding these reductions, please refer to the rules published on the Office of the State Register's website (<http://doa.louisiana.gov/osr>). Complex system changes have resulted in delayed implementation of these reductions. Claims adjudicated prior to implementation of the reductions will be assessed to determine an approach to systematic adjustment. No action is required by providers. Continue to monitor RA's and www.lamedicaid.com for status updates. Contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions related to the implementation of the rate reductions.

Attention CommunityCARE Providers: CommunityCARE Enhanced Fees Ending

Effective August 1, 2010, the CommunityCARE enhanced reimbursement rates for select primary care services ended. CommunityCARE providers will be reimbursed based on the applicable fee on Professional Services Fee Schedule. The CommunityCARE monthly management fee remains in place. Providers will see these changes on the RA of September 28, 2010. Refer to the Office of the State Register's website at <http://doa.louisiana.gov/osr> for published rules detailing these reductions. Providers should visit the LA Medicaid website (www.lamedicaid.com) for updates to the Professional Services Fee Schedule.

Claims for dates of service August 1, 2010 - September 21, 2010 that were adjudicated prior to September 21, 2010 are currently being assessed to determine an approach to a systematic adjustment. No action is required by providers. Continue to monitor future RAs for details regarding when the recycle of these claims will take place. Should you have questions concerning this change, please contact Provider Relations at (800) 473-2783 or (225) 924-5040.

Attention Free Standing End Stage Renal Disease (ESRD) Facilities: Implementation of January 22, 2010 Rate Reductions

Effective with dates of service on or after January 22, 2010, the reimbursement rates for Free Standing ESRD Facilities are reduced by 5%. Complex system changes initially resulted in delayed implementation of these reductions, but they have now been implemented. Providers will begin seeing these reductions on the RA of September 28, 2010. Refer to the Office of the State Register's website at <http://doa.louisiana.gov/osr> for published rules detailing these reductions. Claims that were adjudicated prior to September 21, 2010 are currently being assessed to determine an approach to systematic adjustment. No action is required by providers. Continue to monitor future RA's for details regarding when the recycle of these claims will take place. Contact the Provider Relations unit at (800) 473-2783 or (225) 924-5040 with questions related to the implementation of the rate reductions.

All Providers

Attention Hospital and Physician Providers: Provider Notice for Precertification for OB Care and Delivery

The precertification edit for OB Care and Delivery that went into effect August 30, 2010 was implemented to remove the administrative burden placed on the providers to obtain approval of days that are mandated by federal law. The 2 days approved for a vaginal delivery and 4 days approved for a cesarean section are in accordance with federal guidelines pertaining to the Newborn Protection Act. Days beyond the 2 and 4 days that are approved in accordance with the Newborn Protection Act via the precertification edit are to account for admissions or deliveries late in the evening. Any days approved via the claims processing edit that are greater than the 2 and 4 days mandated by federal guidelines may be subject to medical necessity review retrospectively. Facility specific length of stay reports are generated monthly to compare delivery LOS data pre and post implementation of this policy. Medical necessity should guide the physician decision making process related to discharge and patients should be kept in the hospital for medical necessity only. The precertification edit is not intended to provide approval of hospital days where medical necessity does not exist for continued hospitalization.

Attention Hospital Providers: Provider Notice for Retrospective Review Process

Effective October 18, 2010 hospitals must submit documentation for retrospective reviews per the clarification posted on the Louisiana Medicaid Website. Please visit www.lamedicaid.com and click on the yellow "Acute Precert" button on the left side of the home page. This will bring you to the detailed provider notice concerning this clarification.

Diagnosis Code Update

Effective with date of service October 1, 2010, the 2010 ICD-9 diagnosis codes and operation codes have been added to our files. The files have also been updated to deny those codes now considered invalid. Providers should use the most complete and appropriate diagnosis and operation codes when submitting claims to Louisiana Medicaid.

All Providers

Attention: Providers of Influenza Vaccine

The 2010-2011 seasonal influenza vaccine includes as one of its three components the same H1N1 vaccine used for the 2009-2010 H1N1 pandemic. Also, as of 09/16/2010, the only remaining available 2009-2010 monovalent H1N1 vaccine inventory in circulation reached its expiration and should no longer be used. Therefore, effective 09-16-2010, procedure code 90663 (Influenza virus vaccine, pandemic formulation) will be in non-payable status and claims submitted with dates of service 09/16/2010 and after will deny. Providers submitting claims for the 2010-2011 seasonal influenza vaccine should use the appropriate CPT procedure code for the vaccine formulation administered following current immunization billing policy. Detailed information on the 2010-2011 seasonal influenza vaccine can be found at www.cdc.gov/flu. Contact Molina Medicaid Solutions Provider Relations at (800) 473-2783 or (225) 924-5040 if you should have any questions.

Online Medicaid Provider Manual Chapters

The following Medicaid Provider Manual Chapters are available on the Louisiana Medicaid website at www.lamedicaid.com under the "Provider Manual" link.

- Administrative Claiming
- American Indian 638 Clinics
- Dental
- Durable Medical Equipment
- Family Planning Waiver (Take Charge)
- Home Health
- ICF/DD
- Mental Health Clinics
- Mental Health Rehabilitation
- Multi-Systemic Therapy
- Personal Care Services
- Pharmacy
- Psychological Behavioral Services

This list will be updated periodically as other Medicaid program chapters become available online.

Louisiana Drug Utilization Review Education

Pharmacological Management of Postmenopausal Osteoporosis

Brice Labruzzo Mohundro, PharmD,
Assistant Professor of Clinical Pharmacy Practice, ULM College of Pharmacy
Jennifer Riley Robertson, PharmD,
Earl K. Long PGY-1 Resident

Introduction

Osteoporosis, or "porous bones," is the most commonly occurring bone disease.¹ It is defined as a skeletal disease where low bone mineral density (BMD) and microarchitectural deterioration of bone tissue occur leading to an increase in bone fragility.² According to the U.S. Surgeon General, osteoporosis threatens nearly 55% of people 50 years of age and older. Currently 10 million people in the U.S. over the age of 50 have osteoporosis of the hip. Almost 34 million individuals over age 50 have low bone mass or osteopenia of the hip and are at risk of osteoporosis and its potential complications later in life.³ An estimated one in two postmenopausal white women will have an osteoporosis-related fracture in their lifetime.¹

Pathophysiology

Bones continually change size, shape, and position due to the constant break down of old bone (resorption) and the manufacture of new bone by osteoblasts (formation).³ These processes are kept in balance for most of one's life; however, with advancing age and menopause, resorption occurs more often, leading to decreased bone mass.¹ Bone accumulation peaks at approximately age 20, then bone loss begins to occur. At midlife, bone loss usually speeds up. For most women, bone loss increases after menopause, when estrogen levels drop sharply. In fact, in the five to seven years after menopause, women can lose up to 20 percent or more of their bone density.⁴

Clinical Presentation

Since osteoporosis is a silent disease, patients may be unaware of having low BMD until after a fracture occurs. The most common locations of fracture are the spine, hip, and wrist.¹ BMD is classified by T-score, which is calculated by comparing a patient's BMD to the average peak BMD of a normal young adult of the same gender (Table 1).^{5, 6}

Louisiana Drug Utilization Review Education

Pharmacologic Therapy (Table 2)

Bisphosphonates

Bisphosphonates inhibit osteoclast binding, thereby decreasing bone resorption^{7, 8} and are considered first-line therapy for the treatment of osteoporosis. Bisphosphonates provide the greatest increase in BMD and decrease in fracture risk.⁹ Alendronate has nearly 10 years of data to support its efficacy in reducing long-term fracture risk.⁹ Risendronate has also shown a decrease in both vertebral and hip fracture risk in studies.^{10, 11} Fewer studies support the use of ibandronate; however, the oral iBandronate Osteoporosis vertebral fracture trial in North America and Europe (BONE) showed a 52% reduction in vertebral fractures with intermittent and daily ibandronate use, and the Monthly Oral iBandronate In LadiEs (MOBILE) trial confirmed once-monthly dosing was at least as effective as daily dosing at increasing lumbar spine and proximal femur BMD at year 1.^{12, 13}

Bisphosphonates are poorly absorbed and must be carefully administered to avoid gastrointestinal (GI) side effects. Oral bisphosphonates should be taken first thing in the morning before eating or drinking anything with at least 6-8 ounces of plain water. Patients should remain upright and should not consume any food or medications for 30 to 60 minutes after taking bisphosphonates.^{7, 8}

Most patients prefer once weekly administration of bisphosphonates. Once weekly alendronate has similar BMD results and GI side effects, and does not decrease mineralization compared to daily dosing.¹⁴

Hormone Replacement Therapy

Estrogen increases BMD, but is no longer recommended as first-line therapy for osteoporosis.¹⁵ However, it may be an option for women suffering from vasomotor menopause symptoms. The lowest effective dose should be used for the shortest amount of time possible.¹ Once therapy has been stopped, the patient should be switched to another osteoporosis agent. The Women's Health Initiative trial demonstrated a 33% reduction in vertebral and hip fractures as well as a 23% decrease in other fractures in women taking conjugated estrogen and medroxyprogesterone, although benefits did not outweigh the risks of breast cancer, heart disease, and venous thromboembolism (VTE).¹⁵ Hormone replacement therapy has a black box warning regarding endometrial cancer, cardiovascular, and other risks.

Calcitonin

Calcitonin (Miacalcin®, Fortical®) is considered a second-line agent because it reduces fracture risk less than other available therapies. It is indicated for women at least 5 years post-menopause.^{7, 8} Calcitonin acts as an endogenous inhibitor of bone resorption by decreasing osteoclast function and formation. Kanis and McCloskey demonstrated that treatment with calcitonin was associated with a significant decrease in the number of vertebral and non-vertebral fractures.¹⁶ Calcitonin is also slightly effective at reducing pain associated with acute vertebral fractures.¹⁷

Louisiana Drug Utilization Review Education

Selective Estrogen Receptor Modulators

Raloxifene (Evista®) is the only selective estrogen receptor modulator (SERM) approved for prevention and treatment of osteoporosis in post-menopausal women.⁷ SERMs act as agonists at estrogen receptors in bone tissue and antagonists in breast and uterine tissue.⁷ Large studies have demonstrated an increased BMD in the spine by 2-3% and in the hip by 2.5% after three years of treatment with raloxifene. Although spine fractures decreased by almost 50% and these effects were sustained for up to four years if therapy was continued, no other fracture types were affected by treatment.³ However, patients had decreased total cholesterol and LDL, and decreased risk of newly diagnosed breast cancer.¹⁸ Raloxifene and estrogen both have black box warnings for increased risk of VTE and death from stroke.⁷ Women with active VTE or a history of VTE should not take raloxifene.⁷ Because immobilization increases the risk for venous thromboembolic reactions independent of therapy, raloxifene should be discontinued at least 72 hours prior to and during prolonged immobilization, and should only be resumed after the patient is fully ambulatory.⁷

Denosumab

The newest agent available for osteoporosis is an injectable monoclonal antibody given once every six months.^{7, 20} Denosumab (Prolia®), approved June 2010, exhibits antiresorptive properties by binding to the receptor activator of nuclear factor kappa-B ligand (RANKL) leading to decreased bone resorption and increased BMD.^{7, 20} When given with 1000 mg of calcium and 400 international units of vitamin D, denosumab reduced the incidence of new vertebral and non-vertebral fractures at 3 years.²¹ When compared to once weekly alendronate, denosumab increased BMD at 12 months (3.5% vs 2.6%).²²

Parathyroid Hormone

Recombinant human parathyroid hormone, teriparatide (Forteo®), is the only anabolic agent available for the treatment of osteoporosis.^{1, 7, 8} Teriparatide works by preferentially stimulating osteoblasts when administered once daily.^{7, 8} In a study evaluating once daily teriparatide in postmenopausal women, BMD in the hip increased 3%, while BMD in the spine increased 9%, which led to reductions in non-vertebral and vertebral fractures. Safety and efficacy of teriparatide has not been studied beyond two years of treatment; therefore, the maximum duration of therapy is two years.^{1, 7} Once therapy is complete, patients should begin treatment with a bisphosphonate, which is considered common practice.¹ Because of increased incidence of osteosarcoma in rats, the prescribing information for teriparatide includes a black box warning indicating that it should not be prescribed to patients at increased risk for osteosarcoma.^{1, 7, 8}

Conclusion

Osteoporosis is a disease affecting many women. It is important for clinicians to understand the different effects that various pharmacologic agents have on BMD and fractures. Bisphosphonates should be used as first line therapy in patients without contraindications. In patients who have contraindications or who cannot tolerate bisphosphonates, other agents should be considered.

Louisiana Drug Utilization Review Education

Table 1-World Health Organization BMD Classifications²

Classification	T-Score
Normal	Greater than or equal to -1
Osteopenia	<-1 and > -2.5
Osteoporosis	Less than or equal to -2.5

Table 2-Pharmacotherapy^{7,8}

Drug	Dosage	Adverse Effects	Drug Interactions
Alendronate (Fosamax®)	5 mg daily 10 mg daily 35 mg weekly 70 mg weekly	Nausea, GI irritation, perforation, ulceration and/or bleeding, musculoskeletal pain, osteonecrosis of the jaw	Do not coadminister with any other medication, including calcium
Alendronate/cholecalciferol (Fosamax Plus D®)	70mg/2800mg weekly 70mg/5600mg weekly		
Ibandronate (Boniva®)	2.5 mg daily 150 mg monthly		
Risedronate (Actonel®)	5 mg daily 35 mg weekly 150 mg monthly		
Zoledronic acid (Reclast®)	Glucocorticoid induced and osteoporosis in men: 5 mg IV q 1 year given over no less than 15 minutes -Prevention of osteoporosis: 5 mg IV q 2 years infused over no less than 15 minutes -Treatment of osteoporosis: 5 mg IV q 1 year infused over no less than 15 minutes	Fever, osteonecrosis of the jaw, pain in extremities, myalgia, flu-like symptoms, headache, and arthralgia. The majority of adverse effects occurred within 3 days of infusion; most resolved within 3 days of onset but could take up to 7-14 days	Aminoglycosides, loop diuretics, nephrotoxic drugs, and thalidomide
Raloxifene (Evista®)	60 mg daily	Hot flashes, leg cramps, VTE, stroke	Ampicillin, cholestyramine, highly protein-bound drugs, systemic estrogens, warfarin
Calcitonin Salmon (Miacalcin®, Fortical®)	Intranasal: 200 units daily (alternating nares daily) Injectable: 100 units SQ or IM every other day (effective dose has not been determined, a single study suggests this dose)	Rhinitis, epistaxis	None
Denosumab (Prolia®)	60 mg subcutaneously once every 6 months with 1,000 mg calcium / at least 400 units of vitamin D daily	Dermatitis, eczema, rash, limb pain, hypercholesterolemia, and cystitis	None
Teriparatide (Forteo®)	20 mcg subcutaneously daily for up to 2 years	Pain at injection site, dizziness, leg cramps	Loop diuretics, thiazide diuretics, and digoxin

Louisiana Drug Utilization Review Education

References

1. National Osteoporosis Foundation. *Clinician's Guide to Prevention and Treatment of Osteoporosis*. Washington, DC: National Osteoporosis Foundation; 2010. http://www.nof.org/professionals/pdfs/NOF_ClinicianGuide2009_v7.pdf. Accessed August 16, 2010
2. WHO Scientific Group on the Prevention and Management of Osteoporosis. Prevention and management of osteoporosis: report of a WHO scientific group (WHO technical report series; 921). Geneva, Switzerland: World Health Organization; 2000.
3. US Department of Health and Human Services Office of the Surgeon General. Bone Health and Osteoporosis: A Report of the Surgeon General. www.surgeongeneral.gov/library/bonehealth/content.html. Accessed August 4, 2010.
4. National Osteoporosis Foundation. Bone basics. 2008. <http://www.nof.org/osteoporosis/bonehealth.htm>. Accessed August 16, 2010
5. Heidari B, Hoshmand S, Hajian S, Heidari P. Comparing bone mineral density in postmenopausal women with and without vertebral fracture and its value in recognizing high-risk individuals. *EMHJ*. 2010; 16(8):868-873
6. Siris ES, Barrett-Connor E, Faulkner K, et al. Identification and fracture outcomes of undiagnosed low bone mineral density in postmenopausal women: results from the national osteoporosis risk assessment. *JAMA*. 2001; 286(22):2815-2822.
7. Facts and Comparisons Online. <http://online.factsandcomparisons.com/index.aspx?/> Accessed August 5, 2010
8. Lexi Comp Online. Drug pricing. <http://online.lexi.com/crlsql/servlet/crlonline>. Accessed August 5, 2010
9. Bone HG, Hosking D, Devogelaer JP, et al. Ten years' experience with alendronate for osteoporosis in postmenopausal women. *NEJM*. 2004;350:1189-1199
10. Fogelman I, Ribot C, Smith R, Ethgen D, Sod E, Reginster Y. Risedronate reverses bone loss in postmenopausal women with low bone mass: results from a multinational, double-blind, placebo-controlled trial BMD-MN study group. *JCEM*. 2000;86(6):1895-1900
11. Harris ST, Watts NB, Gnant HK, et al. Effects of risdronate treatment on vertebral and nonvertebral fractures in women with postmenopausal osteoporosis: a randomized controlled trial. *JAMA* 1999; 282(14):1344-1352.
12. Chesnut CH III, Skag A, Christiansen C, et al for the Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe (BONE). Effects of oral ibandronate administered daily or intermittently on fracture risk in postmenopausal osteoporosis. *JBMR*. 2004; 19:1241-1249.
13. Reginster JY, Adami S, Lakatos P, et al. Efficacy and tolerability of once-monthly oral ibandronate in postmenopausal osteoporosis: 2 year results from the MOBILE study. *ARD*. 2006; 65:664-661.
14. Schnitzer T, Bone HG, Crepaldi G, et al. Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis. Alendronate Once-Weekly Study Group. *Aging (Milano)* 2000;12:1-12
15. Writing group for the woman's health initiative investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the women's health Initiative randomized controlled trial. *JAMA* 2002; 288(3):321-333.
16. Kanis JA, McCloskey EV. Effect of calcitonin on vertebral and other fractures. *QJM*. 1999;92:143-149
17. Maksymowych W. Managing acute osteoporotic vertebral fractures with calcitonin. *CFP*. 1998; 44:2160-2166.
18. Barrett-Connor E, Grady D, Sashegyi A, et al. Raloxifene and cardiovascular events in osteoporotic postmenopausal women; four-year results from the multiple outcomes of raloxifene evaluation (MORE) randomized trial. *JAMA*. 2002; 287:847-857. doi10.1001/jama.287.7.847.
19. Jenkins JK. U.S. Food and Drug Administration. New Drug Review: 2009 Update. Office of New Drugs Center for Drug Evaluation and Research FDA/CMS Summit December 3, 2009. Accessed August 10, 2010 <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM192786.pdf>
20. Denosumab (Prolia): A human IgG2 monoclonal antibody that binds to RANKL (or receptor activator of nuclear factor kappa-B ligand), preventing RANKL from activating its receptor (RANK) on the surface of osteoclasts. Formulary 2010 July 1. <http://formularyjournal.modernmedicine.com/formulary/Modern+Medicine+Now/Denosumab-Prolia-A-human-IgG2-monoclonal-antibody-/ArticleStandard/Article/detail/679026>. Accessed August 15, 2010.
21. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc; June 2010.
22. Brown JP, Prince RL, Deal C, et al. Comparison of the effect of denosumab and alendronate on bone mineral density and biochemical markers of bone turnover in postmenopausal women with low bone mass: a randomized, blinded, phase 3 trial. *JBMR*. 2009; 14:1-34.



Provider Relations
 P.O. Box 91024
 Baton Rouge, LA 70821

PRSR STD
 U.S. POSTAGE PAID
 BATON ROUGE, LA
 PERMIT NO. 1037

FOR INFORMATION OR ASSISTANCE, CALL US!

Provider Enrollment	(225) 216-6370	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization			
Home Health/EPSDT - PCS	1-800-807-1320	LaCHIP Enrollee/Applicant Hotline	1-877-252-2447
Dental	1-866-263-6534		
	1-504-941-8206		
DME & All Other	1-800-488-6334	MMIS/Claims Processing/Resolution Unit	(225) 342-3855
	(225) 928-5263		
Hospital Pre-Certification	1-800-877-0666	MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Provider Relations	1-800-473-2783 (225) 924-5040	Medicare Savings Program Medicaid Purchase Hotline	1-888-544-7996
REVS Line	1-800-776-6323 (225) 216-REVS (7387)	KIDMED & CommunityCARE ACS For Hearing Impaired	1-800-259-4444 1-877-544-9544
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	Pharmacy Hotline	1-800-437-9101
		Medicaid Fraud Hotline	1-800-488-2917