Louisiana Medicaid | Provider UPDATE

Volume 30, Issue 8 | May/June 2013

Department of Health and Human Services, Office of Inspector General Updates Bulletins on Effects of Exclusion and Self-Disclosure Protocol

All Providers

The United States Department of Health and Human Services, Office of Inspector General (OIG) has recently released two updated Bulletins. On May 8, 2013 an UPDATED "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs" was released. This is the first update of the Bulletin since its release in 1999. The Bulletin covers the following topics: Statutory Background; Effect of Exclusion from Federal Health Care Programs; Violation of OIG Exclusion by and Excluded Person; Civil Monetary Penalty Liability for Employing or Contracting with an Excluded Person; and How to Determine Whether a Person is Excluded. The full Bulletin can be found at http://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

On April 17, 2013 an UPDATED "OIG's Provider Self-Disclosure Protocol" was released that revised the OIG Self-Disclosure Protocol (SDP) for the first time since October 1998 (http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf). All members of the health care industry have a legal and ethical duty to treat Federal health care programs with integrity, and the SDP establishes a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud, waste, and abuse of Federal health care programs in order to meet this legal and ethical duty. The SDP is available for all health care providers, suppliers, or other individuals or entities subject to Civil Monetary Penalties (CMP) for actions that potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized.

Providers who have employed, contracted, or otherwise done any business with an excluded individual or entity are encouraged to utilize the OIG's SDP. In order for a SDP disclosure to be deemed effective it must include specific and exact information as laid out in the updated notice. Providers are encouraged to review this material meticulously prior to making any disclosures. More information on the SDP can be found at https://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

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Financial Viability Requirements for Providers of Home and Community-Based Services

Providers of Home and Community-Based Services

Providers seeking to obtain a license to provide home and community-based services (HCBS) must adhere to specific statutory requirements for financial viability that include providing verification of and maintaining the following:

- A line of credit issued from a federally insured, licensed lending institution in the amount of at least $50,000,
- General and professional liability insurance of at least $300,000, and
- Workers' compensation insurance.

The Health Standards Section within the Department of Health and Hospitals is responsible for ensuring compliance with these requirements. Before the Health Standards Section will issue an initial HCBS license or renew an existing HCBS license, the following documents must be submitted with the application and applicable licensing fee:

- Documentation of a current line of credit of at least $50,000 that has been written on the lending institution's letterhead and signed and dated by the lending institution's representative. The documentation must include the applicant's name and the geographical location for the agency as identified on the license application.
- Documentation of a general and professional liability insurance policy of at least $300,000 that is current and in effect at the time of submission of the license application.
- Documentation of a workers' compensation insurance policy that is current and in effect at the time of submission of the license application.

A provider's failure to maintain the required line of credit, general and professional liability insurance, and workers' compensation insurance throughout the term of the license constitutes non-compliance with statutory requirements for licensure. This may result in a sanction being imposed including, but not limited to, civil fines, plan of correction, revocation of license, denial of license renewal application, and any and all sanctions allowed under federal or state law or regulation.

The statutory requirements can be found at http://www.legis.state.la.us/lss/lss.asp?doc=321360.

Information is also available on the Health Standards web site for Home and Community Based Services at http://new.dhh.louisiana.gov/index.cfm/directory/detail/719.

Clarification of Credit Balance Audits

All Providers

The responsibility for Credit Balance Audits (CBA), which was being performed by Health Management Systems (HMS) to identify excess Medicaid payments, has changed. Effective January 1, 2013, Health Integrity, LLC assumed this responsibility at the discretion of the Centers for Medicare and Medicaid Services (CMS). Any audits initiated by Health Integrity, LLC must be authorized by CMS.

Providers may send their CBA reports to:
Program Integrity-External Audits Unit
P.O. Box 91030
Baton Rouge, LA 70821-9030

Providers may send secured reports electronically along with any questions and comments to Deanie Vincent at deanie.vincent@la.gov.
Questions concerning audits that were in process before January 1, 2013 should continue to be directed to HMS.

Remittance Advice Corner

All Providers

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

Attention Professional Services Providers:
Medical Review Required for CPT Code 64615

Effective with dates of service beginning April 15, 2013, Medical Review is required for Current Procedural Terminology (CPT) code 64615 (Chemodenervation of muscle(s): innervated by facial…for chronic migraine) to determine if the following criteria have been met prior to allowing payment. For the treatment to be reimbursed using this code, documentation must be submitted with the claim that demonstrates that the patient meets these criteria related to chronic migraine:

- Fifteen or more days of headache or a headache that lasts 4 hours or more per day over 30 days

Please visit http://www.lamedicaid.com for the notice. If you have any questions please contact Molina Provider Relations at (800)473-2783 or (225)924-5040.

Attention Professional Services Providers:
Prior Authorization Required for Brentuximab Vedotin

J9042: Brentuximab Vedotin is a new code included in the HCPCS updates for 2013. Effective April 18, 2013, Louisiana Medicaid will require prior authorization for the chemotherapy drug J9042: Brentuximab Vedotin. Brentuximab Vedotin is a chemotherapy drug used in the treatment of Hodgkin's lymphoma after failure of an autologous stem cell transplant or failure of at least two multidrug chemotherapy regimens. Brentuximab Vedotin is also used for treatment of systemic anaplastic large-cell lymphoma after failure of at least one prior multidrug chemotherapy regimen.

If you have any questions, please contact Molina Provider relations at (800) 473-2783 or (225) 924-5040.

Attention Providers

On March 19, 2013, Judge Brian Jackson issued his Ruling and Order in Joseph Taylor v State of Louisiana, Through the Department of Health and Hospitals, et al, Civil Action Number 09-1068, United States District Court, Middle District of Louisiana declaring LAC 50:1.8341-8349 (Pursuit of the Difference Rule} preempted by existing Federal law to the extent LAC 50:1.8341-8349 permits a health care provider to recoup the balance of its customary payment from third-party settlement proceeds after the provider has accepted payment from Medicaid.
In light of Judge Jackson's ruling, it is the position of the Department of Health and Hospitals/Medicaid Program that medical providers may no longer pursue collection and/or accept payment of the "Difference"; accordingly the "Notification to Louisiana Medicaid" form is no longer being accepted by the Department of Health and Hospitals/Medicaid Program.

Should you have any questions regarding pursuit of and/or acceptance of payment of the "Difference", please contact your legal adviser.

Attention Professional Services and Non-Hospital Ambulatory Providers: 2013 HCPCS Update

The Louisiana Medicaid files have been updated to reflect the new and deleted HCPCS codes for 2013. Providers began to see these changes on the RA of April 2, 2013. Claims denied due to use of the new 2013 codes prior to this update will be recycled once the fee schedules are completed.

Molina is currently updating the Professional Services Fee Schedule on the Louisiana Medicaid Website, http://www.lamedicaid.com.

Additionally, the "Assistant Surgeon/ Assistant at Surgery Covered Procedures List" under the blue "Claim Check" icon on the website homepage has been updated to reflect applicable 2013 procedure codes. As a reminder, "Claim Check" uses the American College of Surgeons (ACS) as its primary source for determining appropriate assistant surgeon designations.

For questions related to this information, please contact Molina Medicaid Provider Services at (800) 473-2783 or (225) 924-5040.

Attention: All Providers Billing Medicaid Recipients for Services

This message is to remind all providers that within your agreement of participation with Louisiana Medicaid you agree to accept the Medicaid payment as payment in full for services rendered to Medicaid recipients,

Remittance Advice Corner - *Continued*

providing for the allowances for co-payments authorized by Medicaid.

A recipient may be billed for services that have been determined as non-covered or exceeding the services limit for recipients over the age of 21. Recipients are also responsible for all services rendered after his/her eligibility has ended. Providers shall not bill recipients in instances where provider billing errors have caused a denied claim. In order to bill a recipient for a non-covered service, the recipient must be informed both verbally and in writing that he/she will be responsible for payment of the services.

NOTE: A recipient delay in receiving authorized Medicaid covered services are prohibited by Louisiana Medicaid.

Attention Professionals and Hospitals Eligible for the EHR Incentive Payment Program

On May 1, 2013, Louisiana Medicaid will launch the NEW AND IMPROVED LAConnect, the online portal for eligible providers to apply for Medicaid EHR incentive payments. On May 1st, eligible professionals and hospitals will be able to access the new system via lamedicaid.com and complete the attestation process for Adoption, Implementation, or Upgrade or Meaningful Use of certified electronic health technology. To attest, go to lamedicaid.com, enter your logon credentials, and click on the LAConnect link.

Primary Care Services Enhanced Reimbursement Update

The deadline to submit a Designated Physician form and receive an effective date for enhanced reimbursement retrospective to January 1, 2013 has been extended further. The deadline is now June 28, 2013. If Molina Provider Enrollment receives your complete and correct form by June 28, 2013, you will receive enhanced reimbursement for eligible services rendered on or after January 1, 2013. If your complete and correct form is received after June 28, 2013, you will receive enhanced reimbursement for eligible services rendered on or after the date the form is received.

If you submitted a Designated Physician form to PRJSM but have not received notice from Molina that it was received, you must submit an original Designated Physician form to Molina. The current Designated Physician form (revised on 4/8/13) can be found at http://www.lamedicaid.com/provweb1/Provider_Enrollment/existingenrollments.htm.

For additional information, please review "ATTENTION PRIMARY CARE PROVIDERS: Affordable Care Act Enhanced Reimbursement of Primary Care Services Informational Bulletin" posted on http://www.lamedicaid.com.

Attention Family Planning Providers

Rate reductions to Family Planning services billed by Physicians and Family Planning Clinics were incorrectly applied as described below. We are systematically adjusting affected claims to correct the error. These adjustments will appear on the May 7, 2013 Remittance Advice.

Physicians

Rate reductions to Family Planning services billed by Physicians were incorrectly applied for dates of service July 1, 2012 through February 19, 2013. A 3.7 percent reduction to rates in effect on June 30, 2012 should have been applied to services rendered during this period. A reduction of 3.4 percent was applied in error.

Rate reductions to Family Planning services billed by Physicians were incorrectly applied for dates of service on or after February 20, 2013. A 3.4 percent reduction to rates in effect on June 30, 2012 should have been applied. A reduction of 3.7 percent was applied in error.

Family Planning Clinics

Rate reductions to Family Planning services billed by Family Planning Clinics were also incorrectly applied for dates of service on or after February 20, 2013. A 3.4 percent reduction to rates in effect on June 30, 2012 should have been

Remittance Advice Corner - *Continued*

applied. A reduction of 3.7 percent was applied in error.

Psychiatric Services: 2013 CPT Changes

In association with the 2013 HCPCS update, Louisiana Medicaid fee for service has established policy related to reimbursement of the new psychiatric diagnostic and psychotherapy procedure codes. Effective with dates of service May 21, 2013 and forward, it is the intent of Louisiana Medicaid to only reimburse providers for these services (currently CPT codes 90791-92 and 90832-90840) when there are face-to-face services where the patient is present and must be clearly documented in the patient record. This policy supersedes recommendations or changes in procedure code descriptions in the Current Procedural Terminology manual for these services. For questions related to this information, please contact Molina Medicaid Provider Services at (800) 473-2783 or (225) 924-5040.

For policy related to Louisiana Behavioral Health Partnership (LBHP), consult the LBHP Services Manuel at http://new.dhh.louisiana.gov/index.cfm/page/538.

Update to 'ClaimCheck' Product Editing

McKesson's 'ClaimCheck' product is routinely updated by McKesson Corporation based on changes made to the resources used, such as Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) coding guidelines, the Centers for Medicare & Medicaid Services (CMS) Physician Fee Schedule database, National Correct Coding Initiative (NCCI) edits, and/or provider specialty society updates. The 'ClaimCheck' product's procedure code edits are guided by these widely accepted industry standards.

The edit changes will affect claims processed beginning with the remittance advice of May 21, 2013 forward. Providers may notice some differences in claims editing that includes pre/post op days, incidental, mutually exclusive, rebundling, add-on and multiple surgery reductions. Providers should expect that some claims will continue to deny for the same error, but when applicable, claims may now pay or deny for a different reason.

With this update, Louisiana Medicaid (claims that process through the Molina claims processing system) also implemented the 2013 quarter one NCCI edits; however, the code pairs specific to preventive services and immunization administration have been deactivated based CMS approval. Doing so aligns with our intent and expectations that appropriate immunizations are to be given at the time of the preventive visit to avoid missed opportunities in both preventive care and immunizations.

Attention Submitters/Providers of Electronic Claims

The deadline for receiving 2013 Annual EDI Certification Forms has passed. If you have not submitted a 2013 Certification form for your submitter number (beginning with 450), immediate action is required. Failure to submit the required form by May 31, 2013 will result in deactivation of the submitter number. If a number is deactivated, the Certification form will have to be received in the Molina EDI Department hardcopy (no faxes or email attachments accepted) before the number is reactivated. This will result in a delay in payment for your providers. If we already received your 2013 form, you or your vendor would have received an email from us confirming receipt. If you have any questions, call the EDI Department at (225) 216-6303.

Attention All Providers 2013 HCPCS Update Completed

The 2013 HCPCS code update is complete and appropriate codes have been added to the Louisiana Medicaid fee schedule effective with the RA of April 02, 2013. Claims billed with 2013 codes that denied prior to this addition are recycled on the 05/14/13 RA. Some claims billed with 2013 codes were paid prior to the implementation of the recent 1% rate reduction retroactive to February 1, 2013. These claims are systematically recycled and paid at the reduced fee on the 05/14/13 RA. No action is necessary by Providers.

Attention Professional Services Providers

Effective with dates of service January 1, 2013 and forward, the following Current Procedural Terminology (CPT) Codes are now payable on the Professional Services Fee Schedule: 81265, 81267, 81380, and 81382. The next fee schedule update should reflect those changes. Providers should resubmit claims as appropriate. For questions related to this information, please contact Molina Medicaid Provider Services at (800) 473-2783 or (225) 924-5040.

Remittance Advice Corner - *Continued*

Attention Professional Services Providers

The Department will be conducting random audits to monitor billing practices relative to delivery/postpartum care. Louisiana Medicaid Fee-for-Service reimbursement policy for postpartum visits requires that providers shall not bill global Current Procedural Terminology (CPT) Codes covering the delivery and the postpartum visit until after the postpartum visit has been completed. Payments for services found to be inappropriately billed may be recouped. For questions related to this information, please contact Molina Provider Services at (800) 473-2783 or (225) 924-5040.

Attention Pharmacists and Prescribing Providers

Pharmacy claims for somatropin for shared health plans or legacy recipients require a valid diagnosis code effective May 28, 2013. Claims submitted without an appropriate diagnosis code will deny with EOB 575. See http://www.lamedicaid.com/

Billing Medicaid Recipients

DHH is receiving many calls from Medicaid recipients stating that they are being billed by providers for Medicare/ Medicaid services. The following is Medicaid policy concerning the processing and payment of Medicare Crossover claims. Providers are responsible for establishing internal billing procedures to ensure that Medicaid recipients are not being inappropriately billed for Medicare/ Medicaid services. Please note that Medicaid does not necessarily pay the full Medicare deductible and co-insurance on a claim. A cost-comparison methodology has been used in the payment of Crossover claims for many years. Providers may not balance-bill recipients in these instances.

Dual eligibles are recipients who have Medicare and Medicaid coverage. Medicaid will reimburse the provider an amount up to the full amount of Medicare's statement of liability for co-insurance and deductible for Qualified Medicare Beneficiaries (QMB).

For claims in which Medicare's reimbursement exceeds the maximum allowable by Medicaid, Medicaid will "zero" pay the claim. This means that the claim will be shown in the Approved Claims section of the RA with a "$0" shown in the payment column. This claim is considered "paid in full" and the provider may not seek additional remuneration from the recipient. Medicaid will pay up to the Medicare deductible and coinsurance on Medicare approved claims for non-Qualified Medicare Beneficiaries (non-QMB) receiving both Medicare and Medicaid, provided the procedure is covered by Medicaid. Medicaid will reimburse the provider an amount up to the full amount of Medicare's statement of liability for co-insurance and deductible as long as it does not exceed Medicaid's allowable reimbursement for the service. Medicaid will "zero' pay the claim when Medicare's reimbursement exceeds the maximum allowable by Medicaid.

If a recipient has both Medicare and Medicaid coverage, providers should file claims in the appropriate manner with the regional Medicare intermediary/ carrier, making sure the recipient's Medicaid number is included on the Medicare claim form. Once the Medicare intermediary/carrier has processed/paid their percentage of the approved charges, Medicare will electronically submit a "crossover" claim to the Medicaid FI that includes the co-insurance and/ or deductible.

If the "crossover" claim is denied by Medicare, the provider must submit a corrected claim to Medicare, if applicable.

If the "crossover" claim is not automatically crossed from Medicare and received by Medicaid, then the provider must submit a hard copy claim for payment of Medicaid's responsibility as appropriate.

Attention Professional Services Providers:
17 Alpha-Hydroxprogesterone Caproate (17P)

Louisiana Medicaid would like to provide clarification regarding policy and current reimbursement of 17 Alpha-Hydroxyprogesterone Caproate (17P). Providers are encouraged to obtain 17P on a proactive basis to have readily available to facilitate usage in the treatment of members at risk for preterm delivery. There is no prior authorization required for Fee-for-Service Medicaid. For complete information related to billing and reimbursement please, refer to the 2010 Policy Update under the Professional Services Program link on the Louisiana Medicaid website (www.lamedicaid.com).
For those recipients in Bayou Health, providers should contact the member's respective Health Plan

Remittance Advice Corner - *Continued*

for information regarding prior authorization requirements.

Billing Multiple Surgical Procedures

Providers are reminded that claims for multiple surgical procedures performed on the same date of service by the same rendering provider must be submitted at the same time. Overpayments due to fragmenting claim submissions are subject to review, recovery of the overpayment and additional sanctions as deemed appropriate by Louisiana Medicaid.

For questions related to this information, please contact Molina Medicaid Solutions Provider Services at (800) 473-2783 or (225) 924-5040.

Online Medicaid Provider Manual Chapters

All Providers

The following Medicaid Provider Manual Chapters are available on the Louisiana Medicaid website at www.lamedicaid.com under the "Provider Manual" link. This list will be updated periodically as other Medicaid program chapters become available online.

Administrative Claiming
Adult Day Health Care Waiver
Ambulatory Surgical Centers
American Indian 638 Clinics
Children's Choice Waiver
Dental Services
Durable Medical Equipment
EPSDT Health and IDEA-Related Services
End Stage Renal Disease
Family Planning Clinics
Family Planning Waiver (Take Charge)
Federally Qualified Health Centers
General Information and Administration
Greater New Orleans Community Health Connection
Home Health
Hospice
Hospital Services
Independent Laboratories
ICF/DD
Medical Transportation
New Opportunities Waiver (NOW)
PACE
Pediatric Day Health Care
Personal Care Services
Pharmacy
Portable X-ray
Professional Services
Residential Options Waiver
Rural Health Clinics
Supports Waiver
Vision (Eye Wear)

A recent revision has been made to the following Medicaid Provider Manual Chapters. Providers should review these revisions in their entirety at www.lamedicaid.com under the "Provider Manual" link:

Online Medicaid Provider Manual Chapters - *Continued*

Manual Chapter	Section(s)	Date of Revision
Home Health	Table of Contents	04/16/13
Professional Services	Appendix G – Podiatry Codes	04/24/13
Children's Choice Waiver	Appendix E – Billing Codes	04/25/13
Medical Transportation	Table of Contents Section 10.2 – NEMT – Service Access and Authorization Section 10.3 – NEMT – Provider Requirements Section 10.4 – NEMT – Provider Responsibilities Section 10.5 – NEMT – Staffing and Training Section 10.6 – NEMT – Record Keeping Section 10.8 – NEMT – Complaint Procedures Appendix G – Contacts Appendix H - Forms	05/10/13

Manual chapters that have been reissued in their entirety or become obsolete remain available for reference under the "Archives" link. The following manual chapters have been moved to this link:

Archived Manual Chapters	
Dental Services	Entire manual reissued March 15, 2012
Elderly and Disabled Adult Waiver	Waiver program ended
EPSDT Health Services for Children with Disabilities	Entire manual reissued March 1, 2013 and renamed EPSDT Health and IDEA-Related Services
Mental Health Clinics	Services that were provided under these programs are now provided through the Louisiana Behavioral Health Partnership.
Mental Health Rehabilitation	
Multi-Systemic Therapy	
Psychological and Behavioral Health	

Current Medication Topics

Louisiana Drug Utilization Review (LADUR) Education

Compiled by the Office of Outcomes Research and Evaluation, University of Louisiana at Monroe College of Pharmacy

Management of Gastroesophageal Reflux Disease (GERD)*

- Weight loss is recommended for GERD patients who are overweight.
- Head of bed elevation and avoidance of meals 2 – 3 h before bedtime should be recommended for patients with nocturnal GERD.
- An 8-week course of PPIs is the therapy of choice for symptom relief and healing of erosive esophagitis. There are no major differences in efficacy between the different PPIs.
- Traditional delayed release PPIs should be administered 30 – 60 min before meals for maximal pH control.
- PPI therapy should be initiated at once a day dosing, before the first meal of the day. For patients with partial response to once daily therapy, tailored therapy with adjustment of dose timing and / or twice daily dosing should be considered in patients with night-time symptoms, variable schedules, and / or sleep disturbance.
- In patients with partial response to PPI therapy, increasing the dose to twice daily therapy or switching to a different PPI may provide additional symptom relief.
- Non-responders to PPI therapy, despite PPI dose optimization, should be referred for evaluation.
- Maintenance PPI therapy should be administered for GERD patients who continue to have symptoms after PPI is discontinued and in patients with complications including erosive esophagitis and Barrett's esophagus. For patients who require long-term PPI therapy, it should be administered in the lowest effective dose, including on demand or intermittent therapy. Step-down therapy to a histamine receptor (H_2RA) antagonist is another option for patients with non-erosive GERD.
- Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The use of PPIs may be associated with increased risk of *Clostridium difficile* associated diarrhea.
- PPIs are safe in pregnant patients if clinically indicated.

Proton Pump Inhibitor (PPI) FDA Approved Adult Dosage and Duration of Therapy for Symptomatic GERD**

PPI	FDA Approved GERD Dosage	Duration of Therapy
dexlansoprazole (Dexilant®)	30 mg daily	4 wks (weeks)
esomeprazole (Nexium®)	20 mg daily	4 wks; may repeat additional 4 wks if not healed
lansoprazole (Prevacid®)	15 mg daily	Up to 8 wks
omeprazole (Prilosec®)	20 mg daily	4 wks
omeprazole/sodium bicarbonate (Zegerid®)	20 mg daily	4 wks
pantoprazole (Protonix®)	***	***
rabeprazole (Aciphex®)	20 mg daily	4 wks; consider additional 4 wks if symptoms do not resolve completely

*Katz P, Gerson L, Vela M. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2013; 108:308-328.
**Dosage and duration of therapy information obtained from prescribing information.
***For short-term treatment of erosive esophagitis associated with GERD: 40 mg daily, duration of therapy 8 wks; may repeat additional 8 wks if not healed

Current Medication Topics - *Continued*

Review of Armodafinil (Nuvigil®) and Modafinil (Provigil®)
• Indications – to improve wakefulness in adult patients with excessive sleepiness associated with the following: o Narcolepsy o Obstructive sleep apnea (OSA), as adjunct to standard treatment(s) ▪ if continuous positive airway pressure (CPAP) is treatment of choice – make maximum effort to treat for adequate period of time before initiating modafinil ▪ if modafinil used with CPAP, encourage and periodically assess CPAP compliance o Shift work disorder (SWD) • Modafinil is not approved for use in pediatric patients (age <17 years) for any indication, including ADHD. • Armodafinil has not been studied in pediatric patients (age <17 years) in any setting and is not approved for use in pediatric patients for any indication. • Careful attention to the diagnosis and treatment of the underlying sleep disorder(s) is of utmost importance. Patients may have more than one sleep disorder contributing to their excessive sleepiness. • Effectiveness of long-term use of modafinil (greater than 9 weeks in narcolepsy clinical trials and greater than 12 weeks in OSA and SWD clinical trials) and long-term use of armodafinil (greater than 12 weeks) have not been systematically evaluated in placebo-controlled trials. Prescribers should periodically reevaluate long-term usefulness for the individual patient.

Modafinil [prescribing information]. Frazer, PA: Cephalon; 2010.
Armodafinil [prescribing information]. Frazer, PA: Cephalon; 2010.

Zolpidem Containing Products: Drug Safety Communication - FDA Requires Lower Recommended Doses

- On 1/10/2013, the FDA issued a Drug Safety Communication regarding lower recommended doses of zolpidem containing products. This announcement focuses on zolpidem products approved for bedtime use, which are marketed as generics and under the brand names Ambien®, Ambien CR®, Edluar®, and Zolpimist®.
- The FDA recommends that the bedtime dose be lowered because new data show that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving.
- For zolpidem products, data show the risk for next-morning impairment is highest for patients taking the extended-release forms of these drugs (Ambien CR® and generics).
- Women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men.
- Because use of lower doses of zolpidem will result in lower blood levels in the morning, FDA is requiring the manufacturers of Ambien®, Ambien CR®, Edluar®, and Zolpimist® to lower the recommended dose.
- Recommendations include:
  - Healthcare professionals should caution all patients (men and women) who use these products about the risks of next-morning impairment for activities that require complete mental alertness, including driving.
  - The recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien®, Edluar®, and Zolpimist®) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR®).
  - The FDA also informed manufacturers that, for men, the labeling should recommend that healthcare professionals consider prescribing the lower doses-5 mg for immediate-release products and 6.25 mg for extended-release products.
  - For zolpidem and other insomnia drugs, prescribe the lowest dose that treats the patient's symptoms.
  - Inform patients that impairment from sleep drugs can be present despite feeling fully awake.
- The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men.

U.S. Food and Drug Administration. (2013, January 10). Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses. Retrieved from

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm

U.S. Food and Drug Administration. (2013, January 10). FDA Requiring Lower Recommended Doses for Certain Sleep Drugs Containing Zolpidem. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm334798.htm

Azithromycin (Zithromax® or Zmax®): Risk of Potentially Fatal Heart Rhythms

- On 3/12/2013, the FDA issued a Drug Safety Communication regarding azithromycin and the risk of potentially fatal heart rhythms.
- The FDA is warning the public that azithromycin (Zithromax® or Zmax®) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm.
- Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias.
- Healthcare professionals should consider the risk of torsades de pointes and fatal heart rhythms with azithromycin when considering treatment options for patients who are already at risk for cardiovascular events.

U.S. Food and Drug Administration. (2013, March 12). Azithromycin (Zithromax® or Zmax®): Drug Safety Communication – Risk of Potentially Fatal Heart Rhythms. Retrieved from http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm343350.htm

MOLINA® Medicaid Solutions

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

29864MMS0213

For information or assistance, call us!

Provider Enrollment	(225) 216-6370
Prior Authorization	
Home Health/EPSDT - PCS	1-800-807-1320
Dental	1-866-263-6534 1-504-941-8206
DME & All Other	1-800-488-6334 (225) 928-5263
Hospital Pre-Certification	1-800-877-0666
Provider Relations	1-800-473-2783 (225) 924-5040
REVS Line	1-800-776-6323 (225) 216-REVS (7387)
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381

General Medicaid Eligibility Hotline	1-888-342-6207
LaCHIP Enrollee/Applicant Hotline	1-877-252-2447
MMIS/Claims Processing/Resolution Unit	(225) 342-3855
MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Medicare Savings Program Medicaid Purchase Hotline	1-888-544-7996
For Hearing Impaired	1-877-544-9544
Pharmacy Hotline	1-800-437-9101
Medicaid Fraud Hotline	1-800-488-2917