Louisiana Medicaid

Provider Update

Volume 24, Issue 5 **September/October 2007**

All Providers

Program of All-Inclusive Care for the Elderly

The Program of All Inclusive Care for the Elderly (PACE) is a capitated model of care which coordinates and provides all needed preventive, primary, acute and long term care services so that older individuals may choose to continue living in the community with appropriate supports. PACE programs generally consist of an adult day health center where primary care physician services and other services are also available.

The PACE organization includes a network of providers similar to a managed care organization and will only pay providers in its network for authorized services. Emergency services may be provided outside of the PACE network, but services must be authorized and paid by the PACE provider. Any service provider treating a PACE enrollee on an emergency basis should contact the PACE provider immediately so that coordination and authorization may be initiated. Medicare and Medicaid will not reimburse any other provider for covered services when the enrollee is linked to a PACE provider.

Unlike other Medicaid services, each PACE site must be approved by the Centers for Medicare and Medicaid Services (CMS). In order to obtain this approval, the potential PACE provider must submit a comprehensive provider application to CMS outlining its operations and specifying the geographic area and number of individuals to be served. This application must be developed in coordination with the Medicaid agency. Once the provider application is approved by CMS, an additional three-way agreement between Medicare, Medicaid and the PACE provider will be executed. Each PACE site may only serve the specific geographic area as denoted in the approved three-way agreement.

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PACE enrollees will be identified when the Medicaid eligibility card is swiped or Medicaid eligibility is verified by telephone or via the web and e-MEVS. A provider will be instructed to contact the PACE provider for authorization of services as PACE, not Medicaid, is responsible for authorization and payment for services rendered to PACE enrollees. The Medicaid claims processing system, including Pharmacy Point of Sale system, will be modified to deny payment of claims submitted for PACE enrollees.

Medicaid enrollees in PACE must be age 55 years old or older, determined by Medicaid to meet nursing facility level of care, live in the PACE provider service area and must be able to live in a community setting without jeopardizing their health or safety at the time of enrollment. Participation in PACE is strictly voluntary. Enrollees may dis-enroll at any time and return to Medicaid fee-for-service at the beginning of the next or second subsequent month, if Medicaid eligibility requirements continue to be met. Enrollment/dis-enrollment in PACE is always at the first of a month and enrollees will be identified in Medicaid eligibility systems as PACE enrollees.

PACE programs are required to provide all Medicare and Medicaid covered services including:

- Physician services
- Transportation
- Inpatient and outpatient hospital services
- Social Work
- Nursing facility care services
- Rehabilitation therapy
- Adult Day Health Care
- Personal care services
- Drugs and biologicals
- Nutrition therapy
- Lab, X-rays, and diagnostic procedures
- Recreation therapy
- Medical specialty services
- Durable medical equipment, prosthetics, orthotics, and supplies

Medicaid and/or Medicare will reimburse PACE a monthly capitated payment.

Implementation of the PACE Greater New Orleans (GNO) program began September 1, 2007. The service area for PACE GNO includes only the following zip codes in: Orleans (70112, 70113, 70114, 70115, 70116, 70117, 70118, 70119, 70122, 70124, 70125, 70126, 70127, 70128, 70129, 70130, 70131), St. Bernard (zip codes 70032 or 70043) and Jefferson Parishes (70001, 70002, 70003, 70005, 70006, 70053, 70161, 70121). Note: These zip codes do not include all zip codes for the three parishes. If a Medicaid recipient is enrolled in PACE, PACE GNO may be contacted at **(504) 945-1531** to request authorization and payment of services provided to PACE enrollees.

A second program, Franciscan PACE Baton Rouge (PACE BR) will be implemented in the spring of 2008. The service area for PACE BR will be all of East Baton Rouge and West Baton Rouge parishes. Ascension and Livingston parishes are expected to be phased in within 24 months.
Providers should always verify eligibility on every visit to assure that a Medicaid recipient is eligible for fee-for-service payment.

Urgent NPI Notice

Although the mandated date for implementation of National Provider Identifiers (NPI) was officially extended by the Centers for Medicare and Medicaid Services (CMS), the requirement for medical providers to obtain and use NPIs is still imminent and necessary. Louisiana NPI implementation is quickly approaching and your NPI is needed. Register your NPI now by accessing the provider secured site at www.lamedicaid.com.

Please remember that once you have applied for and received an NPI, it is necessary for you to register all NPIs with Unisys (fiscal agent for the Louisiana Medicaid Program). All NPIs that correspond with Louisiana Medicaid provider numbers must be registered. NPIs are not automatically transferred to Unisys by the vendor assigning them.

Updated information will be posted on the LA Medicaid website, RA messages, provider notices, and Provider Update articles. The final compliance date for Louisiana Medicaid NPI implementation will be announced by DHH through these avenues. Review all provider publications and monitor the web site frequently to stay informed about the NPI implementation. ***Please note that for all currently enrolled providers who are required to have an NPI, this number is now required for all transactions with Provider Enrollment, such as the following interim change requests: Direct Deposit, Address Change, Group Linkages, etc. If you have not applied for an NPI, you must do so before requesting any changes to your Provider file.***

If you have a special circumstance where you have multiple NPIs for one Louisiana Medicaid provider number or multiple Louisiana Medicaid provider numbers for one NPI, please contact the Unisys NPI group at (225) 216-6400 or via e-mail at LAMEDICAIDNPI@unisys.com for assistance.

ACT NOW…TIME IS RUNNING OUT!!
Register Your NPI(s) With Louisiana Medicaid. Failure to register NPIs timely may result in interruption of claims payment.

Update on Medicaid Programs for Children

During the 2007 Regular Session of the Louisiana Legislature, a resolution was passed to urge and request funding for the Family Opportunity Act, a federal initiative to provide health coverage to uninsured children with disabilities in families who are not financially eligible for Medicaid or LaCHIP. This program started accepting applications on October 1, 2007.

Currently, the LaCHIP and Medicaid Programs offer coverage for children in families with income up to 200 percent of the Federal Poverty Level (FPL). Through the Family Opportunity Act, Medicaid provides coverage to children with disabilities in families with income up to 300 percent of the FPL by allowing the families to buy in to the Medicaid Program. In addition to allowing family income to be equal to or less than 300 percent of the FPL, qualifying applicants must be 12 years of age or younger and must have a physical or mental condition that is disabling according to Social Security Administration disability criteria. The Medical Eligibility Determination Team will review the clinical information and make a decision.

The benefits package offered through the Medicaid and LaCHIP Programs is available to enrollees under this new eligibility category and there is no waiting period for coverage. These children may have other insurance coverage, but Medicaid will always be the payer of last resort. The monthly premium for Family Opportunity Act Medicaid is $35 for uninsured children and $15 for those children with insurance.

A program-specific application is in development, but anyone wishing to apply now can fill out the general Medicaid application. Application forms are available online at www.medicaid.dhh.louisiana.gov, by calling the Medicaid office at 1-888-342-6207 or through parish Medicaid offices and local Medicaid Application Centers.

The Presidential veto of the SCHIP legislation will not alter the Family Opportunity Act. However, the veto does have the potential to impact LaCHIP. The program will continue to operate fully funded until November with the extension granted by Congress. Because of the Presidential veto, Congress has two choices: they can vote to override the veto, or work toward a compromise. If the SCHIP bill fails to be reauthorized, the Department of Health and Hospitals (DHH) will continue to cover children using available funds. However, LaCHIP will not be expanded nor will federal funding be available to support the program through the remainder of the fiscal year. If the bill is not reauthorized, DHH will revise the program and its funding in early 2008.

Emergency Preparedness Web Site for Nursing Facilities

The Louisiana Department of Health and Hospitals (DHH), Health Standards Section has created a web-site to provide operational information about nursing facilities located in Louisiana. All nursing facilities in the State of Louisiana are required to update their information on a monthly basis or as requested by DHH.

The updating of this website will replace the current required process of faxing in current census information. Facilities will no longer be required to fax current census information. Instead all nursing facilities should go to the Health Standards Section Emergency Preparedness website. You may easily access the website by typing **dhhincidenttracking.dhh.louisiana.gov/Facility/Facility.aspx** in the address field of your Internet browser. You may also access it through the Health Standards Section Internet home page by entering **http://www.dhh.louisiana.gov/offices/?ID=112**, scroll down to "Featured Services", and left click "Emergency Preparedness Website - Nursing Home Emergency Information".

Questions regarding the use of this website or passwords should be directed to:

Malcolm H. Tietje, Program Manager
Nursing Home Emergency Preparedness
(225) 342-2390
mtietje@dhh.la.gov

or

Mary Veals, Program Specialist
Nursing Home Emergency Preparedness
(225) 342-3240
mveals@dhh.la.gov

Questions regarding information discrepancies or requests to add, modify or delete username and passwords should be directed to:

Kay Morris
Nursing Home Program Desk
(225) 342-0114, fax (225) 342-5292
lkmorris@dhh.la.gov

Hospice Providers

Policy Clarification

The following information clarifies Hospice Program policy regarding signature requirements:

- In cases where a patient signs the Notice of Election form with an "X", two witnesses must sign next to the patient's mark.
- Hospice services end when a patient's Medicaid eligibility ends. A new Notice of Election form and Certificate of Illness form is required with updated signatures whenever he/she is recertified for Medicaid. Providers are encouraged to contact family members regarding the patient's Medicaid coverage.
- Two signatures are required on the Certificate of Illness form, an admitting/attending physician **and** the hospice medical director.
- The patient's or the authorized representative's signature is required whenever a patient receiving "Medicaid only" revokes hospice.

Waiver Services Providers

General Information Concerning Documentation Requirements

It is the responsibility of the support coordination agency and direct service provider agency to provide adequate documentation of services provided to waiver participants for the purposes of continuity of care/support for the individual and the need for adequate monitoring of progress toward outcomes and services received. This documentation is an on-going chronology of activities undertaken on behalf of the participant.

Progress notes must be of sufficient content to reflect descriptions of activities. They cannot be so general that a complete picture of the services and progress cannot be drawn from the content of the note, i.e., general terms such as "called the participant," "supported participant" or "assisted participant" is not sufficient and does not reflect adequate content. Checklists alone are not adequate documentation.

Service logs must support the billed activity and provide sufficient narrative documentation/information to clearly identify the activity and the participants. The Office of Aging and Adult Services (OAAS) and the Office for Citizens with Development Disabilities (OCDD) allow the support coordinators and the direct service providers of waiver services to utilize the service log to document required "progress notes" and "progress summaries."

OAAS and OCDD do not prescribe a format for waiver documentation, but require that all of the components outlined below are included. The schedule for documentation differs based on each waiver/service system. Detailed information regarding scheduling requirements can be found at www.lamedicaid.com.

All notes, summaries and service log entries in a participant's record should include:

- Name of author/person making entry
- Signature of author/person making entry
- Functional title of person making entry
- Full date of documentation
- Signature or initials indicating review by supervisor, if required
- Legible entries written in ink, if handwritten
- Narrative that follows definition for the type of documentation used.

Long Term-Personal Care Services
Service Logs Documentation

The Office of Aging and Adult Services would like to issue the following reminders concerning documentation of services logs for Long-Term Personal Care Services (LT-PCS).

Do:

- Follow the care plan as written
- Provide specific tasks on the specified days in the time allotted
- Document the reason a task is not provided or the reason it is not provided as scheduled
- Subtract the time for a task not provided from the time billed
- Provide **only** the services listed on the care plan
- Ensure that service logs are filled out carefully and correctly
- Only bill for the tasks provided
- If a client receives more than one service; e.g., Elderly and Disabled Adult (EDA) Waiver and LT-PCS, you must use a separate service log for each service
- Check service logs for accuracy and completeness
- Submit service logs that are in original, handwritten form

Don't:

- Routinely move tasks or time to different days than are shown on the care plan
- Turn a 7 day care plan into a 5 day care plan or vice versa
- Fail to document differences from the care plan and the reason for the difference
- Bill when a task is not performed (*e.g.*, if the client doesn't get a bath on a given day it is not allowable to bill for that bath)
- Bill for tasks not on the care plan
- Submit service logs with numerous alterations. If errors are made, make corrections according to Medicaid policy
- Show tasks from more than one program on the same log
- Submit logs without required dates, times and signatures
- Photocopy prior filled out service logs and change the date

Pharmacy Providers

Several recent Federal statutes have provisions which affect billing and reimbursement of Medicaid pharmacy claims. We are providing updated information pertaining to these provisions including the National Provider Identifier (NPI), Tamper-resistant Prescription Pads and changes to the Federal Upper Limits with regard to the Deficit Reduction Act of 2005.

National Provider Identifier (NPI)

Effective August 19, 2007, a transition period which allowed the billing of Point of Sale pharmacy claims to Louisiana Medicaid with either the provider's Medicaid number or the provider's National Provider Identifier (NPI) began.

The NCPDP 5.1 format permits only a single billing pharmacy identifier, thus the qualifiers will become very important data elements for determining the type of identifier submitted during the transition period.

The Department of Health and Hospitals (DHH) is advising Pharmacy providers to contact their software vendor to insure that their software is able to transmit an NPI, since programming changes or a change in the software "set-up" for Medicaid billing may be required.

A date for accepting NPI-only for the pharmacy billing has not been determined although it is anticipated that this will take place prior to May 23, 2008. Also, no determination has been made regarding accepting NPI-only for the prescriber. Louisiana Medicaid plans to make registered prescriber numbers available to pharmacies and their software vendors as soon as a significant number are available.

At this time, it is necessary to continue completing the NCPDP Universal Paper Claim Form with the Medicaid ID and not the NPI for both the pharmacy and prescriber fields.

Pharmacy providers have received a detailed letter regarding claim submission with the NPI and appropriate qualifiers. Any questions regarding the billing of pharmacy claims with NPIs should be directed to the Pharmacy POS Helpdesk at 1-800-648-0790 or 225-216-6381.

Deficit Reduction Act of 2005 and Federal Upper Limits

The Deficit Reduction Act of 2005 (DRA) enacted significant changes to payment for prescription drugs by the Medicaid Program. The DRA changes the methodology to calculate a Federal Upper Limit (FUL) on certain multisource prescription drugs. The FUL will now be established for each multiple source drug for which the Federal Drug Administration (FDA) has rated two or more products as therapeutically equivalent, regardless of other formulations. Section 6001(a)(3) of the DRA changed the definition of multiple source drugs to include a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent. The FUL calculation will use 250% of the Average Manufacturer Price (AMP) for the least costly therapeutic equivalent as the formula for establishing an FUL on multiple source drugs.

The Final Rule was published in the Federal Register on July 17, 2007 and is available at http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms2238fc.pdf.

The timeline issued by CMS states that the effective date of the new FULs will be January 30, 2008. As policy regarding the new FULs is implemented, Louisiana Medicaid will inform pharmacy providers with detailed correspondence.

Tamper-Resistant Prescription Pads

A provision in the "U.S. Troop Readiness, Veterans' Health Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007" (H.R. 2206) requires the use of tamper-resistant prescription drug pads for written, non-electronic prescriptions for Medicaid recipients. This provision was to be effective October 1, 2007. However, the "TMA, Abstinence Education and QI Program Extension Act of 2007" (H.R. 3668) was enacted, thus delaying the implementation until **April 1, 2008**.

Guidance from The Centers for Medicare and Medicaid Services (CMS) allows a prescription pad to be compliant on or after April 1, 2008, if one of the following three characteristics is met:

- One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber;
- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

No later than October 1, 2008, to be considered tamper-resistant, a prescription pad must contain **all three** characteristics listed above.

This provision applies to all written (non-electronic) prescriptions:

- For outpatient drugs including over-the-counter drugs reimbursed by the Medicaid Pharmacy Program;
- Regardless of whether Medicaid is the primary or secondary payer.

The tamper-resistant requirement does not apply to prescriptions which are:

- Communicated by the prescriber to the pharmacy electronically, verbally or by facsimile;
- Refills of written prescriptions presented at the pharmacy prior to April 1, 2008.

Emergency fills with non-compliant written prescriptions are permissible as long as the prescriber provides a verbal, faxed, electronic or compliant written prescription within 72 hours. If an emergency fill is confirmed with a verbal order, the pharmacist must document the call on the face of the written prescription.

It is the responsibility of the prescriber to obtain and purchase tamper-resistant prescription pads.

Medicaid will notify pharmacy providers and prescribing practitioners of further guidance and policy regarding the use of tamper resistant prescription pads.

Home and Community-Based Service Providers

Direct Service Worker Registry

Act 306 of the 2005 Regular Legislative Session directed the Department of Health and Hospitals (DHH) to establish and maintain a registry for direct service workers (DSW). A direct service worker is an unlicensed person who provides personal care or other services and support to persons with disabilities or the elderly to enhance their well-being, involving face-to-face direct contact with the person. The registry will maintain the names of individuals who, either by work history or training, are eligible to be registered as a direct service worker. The registry will also allow potential employers to determine if the worker is in good standing with no findings of abuse, neglect, misappropriation or exploitation against them. The Department published a final rule outlining training requirements for direct service workers in the November 20, 2006 Louisiana Register. The provider types licensed by DHH that are affected by registry requirements include intermediate care facilities for the mentally retarded (also referred to as intermediate care facilities for the developmentally disabled), personal care attendant, supervised independent living, respite, adult day care and adult day health care.

The registry is now operational and can be accessed online at www.labenfa.com, then click on the link 'Nurse Aid/DSW Registry'. When the screen opens, enter the Social Security number of the DSW and click on "Search". Providers are required to verify the status of workers, via the registry, prior to making an offer of employment. If you are unable to access the registry from this website, you may call 225-295-8575 for assistance.

Providers who previously submitted DSW 9 (Grandfather) forms for employees who have a work history of at least 18 months prior to November 20, 2006, should be assured the information concerning those workers will be placed on the registry as soon as possible, if they are not entered already. All DSW 9 (Grandfather form), DSW 8 (Verification of Completion of DSW Training Course) and DSW 7 (Verification of Employment/Termination) forms should be submitted directly to the registry. Please remember that you are not allowed to provide training to workers unless your curriculum has been approved by the Department. Questions related to placement of workers on the registry may be directed to Cathy Oglesby at DSW registry, 225-295-8575. Questions regarding approval of training curriculum/other registry requirements may be directed to Candace Andrus, RN Program Manager (225-342-5794).

Case Management Providers

Staffing Qualification Changes for Case Management Services

Due to the critical shortage of staff for case management (also referred to as support coordination) agencies, it was necessary for the Department of Health and Hospitals to implement modifications to the provisions governing staff qualifications contained in LAC 48:I.4901., Case Management Licensing Standards, and LAC 50:XV.10505., Targeted Case Management, in the interim period while the routine promulgation procedures for revision are pursued.

Effective immediately, anyone hired or promoted on or after August 20, 2007, must meet the new qualifications for case managers (support coordinators) and case manager supervisors. A copy of the memorandum to case management agencies regarding these new staff qualifications can be viewed on line at the Health Standards Section (HSS) website, http://www.dhh.louisiana.gov/offices/publications.asp?ID=112, by scrolling down to Provider Memos, and clicking on "Case Management Staff Qualifications" dated August 31, 2007.

We are hopeful that this change in staff qualifications will alleviate the critical hiring shortage while maintaining the quality of services being provided.

If you have any questions you may contact Terry Cooper, RN, at (225) 342-2795 or Lynn Nicholson, RN, at (225) 342-2957 with Health Standards.

Reimbursement for Inpatient Concurrent Care for Adults

Effective for dates of service on or after January 1, 2007, Louisiana Medicaid reimburses for adult concurrent care. Inpatient concurrent care is defined as the provision of services by more than one physician to a patient on the same day.

Louisiana Medicaid reimburses up to three medically necessary hospital inpatient service visits per day for adult recipients (aged 21 years and older) for providers of different specialties/sub-specialties.

Concurrent care services are necessary when a patient's condition and/or diagnosis(es) require the services of more than one physician to assure that the patient receives the appropriate standard of treatment. Concurrent care must be medically necessary, unduplicated, and reasonable.

The intent of the Department is to reimburse one provider per specialty or sub-specialty per day per recipient with a maximum of three paid visits. If more than one inpatient service/consultation is paid to a provider of the same specialty on the same date of service, the payment is subject to post-payment review and recovery.

- One code from the current initial hospital care code range 99221-99223 can be reimbursed per **inpatient stay** to the admitting provider.

- An attending provider may be reimbursed for **one** inpatient hospital care service per day per recipient. If a patient must be seen by the same provider more than once daily, the level of code billed for that date should reflect all the services rendered that day.

- Inpatient consultation codes (current code range 99251-99255) are included in the three medically necessary hospital inpatient service visits allowed per day.

- An inpatient consultation service and an outpatient visit, including an Emergency Department visit, cannot be reimbursed to the same attending provider for the same date of service, as the consultation no longer meets Louisiana Medicaid criteria for a consultation.

Only one consultation service (current code range 99251-99255) should be reported by a consultant per admission. For a consultation service to be reimbursed, the consultation criteria must be met, as described in the Consultation section of the Professional Services Provider Training manual. Subsequent services during the same admission are reported using "Subsequent Hospital Care" codes (currently 99231-99233), including services to complete the initial consultation, monitor progress, revise recommendations, or address a new problem. (See *Current Procedural Terminology [CPT]* guidelines).

Hospital Discharge Services (currently 99238, 99239) are included in the limit of three inpatient visits per day. An attending provider cannot be reimbursed for an inpatient service and a hospital discharge service on the same date of service. Only one provider may be reimbursed for the hospital discharge service code (99238 or 99239) per inpatient stay.

Preventive Medicine Evaluation and Management Services

Effective for dates of service on or after July 1, 2006, Louisiana Medicaid began reimbursing preventive medicine services for adults ages 21 years and older. Providers must use the appropriate Preventive Medicine Services "New Patient" or "Established Patient" CPT code based on the age of the recipient when submitting claims for the services. The preventive medicine services are included in the 12 outpatient visit service limit allowed per calendar year.

One preventive medicine service will be reimbursed per recipient per calendar year. The information gathered during the preventive medicine visit should be forwarded to any requesting provider in order to communicate findings and prevent duplicative services.

Preventive Medicine Services CPT codes are comprehensive in nature and should reflect age and gender specific services. Separately reported screening procedures performed by the physician or referrals for those services should be based on nationally recognized standards of care/best practices (screening mammography, prostate cancer screening, etc.).

The medical record documentation must include, but is not limited to:

- Physical examination;
- Medical and social history review;
- Counseling/anticipatory guidance/risk factor reduction intervention;
- Screening test(s) and results.

If any abnormality or pre-existing problem is encountered and treatment is significant enough to require additional work to perform the key components of a problem oriented Evaluation and Management (E/M) service on the same date of service by the provider performing the preventive medicine service visit, no office visit of a higher level than CPT code 99212 is reimbursable.

Providers and recipients need to be aware that if two acceptable Evaluation and Management codes are paid on the same date of service, both services will apply to the 12 outpatient visit service limit. Providers should assist recipients in the management of their limited yearly outpatient visits.

Payments to providers are subject to post payment review and recovery of overpayments.

RA Message Corner

Error Code 515 Claim Denial Simplification Process

Currently, certain procedure codes are eligible for reimbursement by Medicaid when rendered as a second restoration on the same patient, same tooth within a 12 month period due to pulpal necrosis or traumatic injury. Claims for this situation currently receive an error code 515 claim denial (override required-send to dental PA unit) which requires further action by the provider in order to receive reimbursement. Effective September 13, 2007, a new method of handling these claims was implemented by Medicaid regardless of the date of service. When the new method is followed, eligible claims will not deny for the 515 error code and will pay without further action required from providers. Providers may obtain detailed information at www.lamedicaid.com under the link entitled "new Medicaid information" or "billing information". Questions regarding the new policy should be directed to the Medicaid Dental Unit by calling 504-941-8206. If you do not have computer access and require a hardcopy of the detailed information, contact Unisys Provider Relations by calling 225-924-5040 or 1-800-473-2783 (toll-free).

The Deficit Reduction Act of 2005, Section 6032 Implementation

As a condition of payment for goods, services and supplies provided to recipients of the Medicaid Program, providers and entities must comply with the False Claims Act employee training and policy requirements in 1902(a)(68) of the Social Security Act, set forth in that subsection and as the Secretary of the U.S. Department of Health and Human Services may specify. As an enrolled provider/entity, it is your obligation to inform all of your employees and affiliates of the provisions of the Federal False Claims Act, and any Louisiana laws and/or rules pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws and/or rules. When monitored or audited, you will be required to show evidence of compliance with this requirement.

This provision requires any entity that receives annual Medicaid payments under the State Plan of at least $5 million to provide Federal False Claims Act education to their employees.

MSA Code Changes

Effective with dates of service beginning October 1, 2007, the Metropolitan Statistical Assignment (MSA) codes currently used for billing hospice services in the following parishes have been changed to:

Cameron-3960	Grant-0220	Desoto-7680	E. Feliciana-0760
Iberville -0760	Pointe Coupee-0760	St. Helena-0760	Union-5200

New Telephone Number for the Drug Information Center

The Drug Information Center (DIC) at The University of Louisiana at Monroe College of Pharmacy has a new telephone number and a new focus on service to healthcare providers. This service is available to Louisiana Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program.

Services provided include:

- ***Literature retrieval***
- ***Evidence-based advice***
- ***Drug dosage***
- ***Extemporaneous preparations***
- ***Lab-related inquiries***
- ***Pregnancy and lactation***
- ***Drug interactions***

As a Louisiana Medicaid provider, this service is free to you. Remember to call 318-342-5501 with your drug- and pharmacy-related questions.

The Role of the Incretin System in the Treatment of Type 2 Diabetes

By: Tibb F. Jacobs, Pharm.D., BCPS
Assistant Professor
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Type 2 diabetes is a major health threat in the United States. The rate of death from heart disease and stroke is two to four times higher in patients with diabetes. Diabetes is also the leading cause of blindness, amputation, and end stage renal disease (ESRD) in the United States. The importance of adequately treating patients with type 2 diabetes cannot be underestimated. Standards of care in patients with type 2 diabetes indicate all patients should be treated to a hemoglobin A1C of less than 7%; however, only 40% of patients with diabetes successfully reach this goal. This highlights the necessity of developing new treatments for patients with type 2 diabetes.

Medications for Type 2 Diabetes

Hyperglycemia in type 2 diabetes is attributable to several factors; typically type 2 diabetes is thought of as a dysfunction of the pancreatic beta cells with a background of insulin resistance. In addition to the aforementioned dysfunction, patients with type 2 diabetes also experience pancreatic alpha cell defects as well as inappropriate hepatic glucose production. In the past, available medications have not targeted all of these sites. The following table lists medications available for treatment of type 2 diabetes prior to the use of incretin related medications:

Medication	Mechanism of Action (MOA)	Adverse Drug Events (ADE)	A1C Decrease	Comments
Metformin	Decrease hepatic glucose production; increase glucose uptake (muscle)	Significant GI upset (cramping and diarrhea) on initiation	1.5-2%	• Modest weight loss • First line therapy according to ADA • Contraindicated in renal impairment and hepatic disease
Sulfonylureas (such as glipizide, glyburide, glimepiride)	Enhance endogenous insulin secretion from pancreatic beta cells	Weight gain, hypoglycemia	1.5-2%	• Lose efficacy over time
Non-sulfonylurea secretagogues Prandin® (repaglinide), Starlix®, (nateglinide)	Enhance endogenous insulin secretion from pancreatic beta cells	Weight gain, hypoglycemia	0.8-1%	• Shorter acting than sulfonylureas • Dosed with meals • Contraindicated in hepatic dysfunction
Insulin	Replaces or supplements endogenous insulin	Weight gain, hypoglycemia hypokalemia	--	• Contraindicated with hypoglycemia and hypokalemia • Requires more careful patient monitoring
Thiazolidinediones (TZDs) Actos® (pioglitazone), Avandia® (rosiglitazone)	Insulin sensitizers; enhance glucose uptake in adipose and muscle tissues	Weight gain, edema, can potentiate CHF exacerbations, increased LDL (rosiglitazone)	1.5%	• Caution with CHF patients • Recent reports of increased risk of MI with rosiglitazone
Alpha glucosidase inhibitors Precose® (acarbose), Glyset® (miglitol)	Block degradation of complex carbohydrates in small intestine	Severe GI symptoms (especially flatulence)	0.3-1%	• Affect post prandial glucose levels • Contraindicated in GI disease/obstruction, IBD, renal failure • Significant drug interactions; administer separately from other drugs

American Diabetes Association (ADA) Treatment Recommendations

The ADA recently released treatment guidelines for patients with type 2 diabetes stating that metformin and lifestyle modifications should be used initially in all patients without contraindications. If A1C goal is not met with metformin monotherapy, then one of three second line agents can be added. Currently, TZDs, sulfonylureas, and insulin are considered second line agents. If a patient's goals are still unmet, then insulin therapy should be initiated or intensified. Several medications are not included in this ADA algorithm; this is because of less impressive reductions in A1C and/or a lack of available trial data at the time of publication.

The Incretin Effect

The incretin system represents a novel treatment pathway for patients with type 2 diabetes. The 'incretin effect' was first identified by administering oral and IV glucose to patients without diabetes and testing insulin levels. It was discovered that there is a huge spike in insulin production in healthy patients receiving oral glucose (three times greater insulin production) compared to IV glucose. This led to the theory of gut hormones responsible for this insulin secretion. The **incretin effect** is defined as the difference in insulin response to oral versus IV glucose loads. Eating promotes the secretion of multiple GI hormones involved in regulation of gut motility and stimulation of insulin secretion. In healthy patients, up to 50% of the post-prandial insulin secretion is the result of the incretin effect.

Two gut hormones have been identified: Glucose dependent insulinotropic hormone (GIP) and glucagon like peptide-1 (GLP-1). Secretion of GLP-1 is impaired in patients with type 2 diabetes. GLP-1, which is secreted in response to nutrients, enhances insulin secretion in a glucose dependent manner, and is produced in L cells of the small intestine. GLP-1 exerts its main effect by stimulating glucose dependent insulin release from pancreatic beta cells. In addition, GLP-1 slows gastric emptying, inhibits inappropriate postmeal glucagon release from the pancreatic alpha cells, and promotes satiety, thereby decreasing food intake.

GLP-1 has a very short half life (plasma half life <1 minute); it is degraded almost immediately by the dipeptidyl peptidase-4 enzyme (DPP-4). Presently, strategies are being aimed at developing GLP-1 analogues and receptor agonists (incretin mimetics) that resist degradation by DPP-4, as well as agents that inhibit DPP-4 resulting in increased levels of endogenous GLP-1.

Current Incretin Treatment Options

There are presently two incretin treatment strategies currently available and several others on the horizon. As mentioned earlier, there are the GLP-1 agents and the DPP-4 inhibitors. Of the GLP-1 agents, only exenatide (Byetta®) is currently available. Exenatide LAR (once weekly dosing) and liraglutide (once daily dosing) are still in development. There are several DPP-4 inhibitors still in clinical trials, including vildagliptin (Galvus®) and saxagliptin. Only sitagliptin (Januvia®) has currently received FDA approval.

Exenatide (Byetta®)

Exenatide (Byetta®) is the first in a new class of incretin mimetics. It enhances glucose dependent insulin secretion, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying. Exenatide is derived from exendin 4, which is found in the salivary gland of the Gila monster. Since it is a synthetic GLP-1 agonist, it resists degradation by DPP-4.

Exenatide is indicated only as an adjunct therapy for treatment of type 2 diabetes. It can be used in combination with metformin, sulfonylureas, TZDs, metformin + TZD, or metformin + sulfonylurea. Exenatide is available as a prefilled pen in a 5 mcg or 10 mcg dosage; each pen delivers 60 doses. Patients will need to purchase pen needles separately. Exenatide is typically administered via subcutaneous injection 60 minutes before morning and evening meals. Therapy is initiated with the 5 mcg dose; titration to the 10 mcg dose can be done after 4 weeks of treatment at the lower dose. Exenatide is predominately renally excreted; therefore, it is not recommended in patients with severe renal impairment. Exenatide is also not recommended in patients with severe gastrointestinal disease due to its gastrointestinal side effects.

Many patients (40%) experience nausea upon initiation of therapy; other common side effects seen in trials are vomiting, diarrhea, jitteriness, headache, and injection site reactions. With continuation of therapy, the GI side effects decrease. Hypoglycemia is not seen when Byetta is combined with metformin; however, when Byetta® is used with the sulfonylureas, the risk of hypoglycemia is increased. Despite the nausea upon therapy initiation, many patients are willing to try Byetta® because of the weight loss seen with this product. In trials of up to 30 weeks, weight loss of up to 3 kg is seen; in longer trials, lasting 82 weeks, average weight loss is 4.4 kg. Patients with larger baseline BMIs (>40) had a greater mean reduction in weight than patients with smaller BMIs (<25); 7 kg of weight loss versus 2 kg, respectively.

Due to Byetta's® effect on gastric emptying, it should be used cautiously with medications requiring rapid GI absorption. Caution patients to take medications such as oral contraceptives and antibiotics at least one hour before a Byetta® injection. There have been some cases of increased INR in warfarin patients using exenatide concomitantly.

Byetta® was approved based on three clinical trials lasting 30 weeks; the trials contained a total of 1446 patients. Byetta® was studied in combination with metformin, sulfonylureas, and metformin + sulfonylurea. When compared to placebo, sustained weight loss was seen in all three studies. Decreases in A1C of 0.8% were seen when exenatide 10 mcg BID was combined with metformin, 0.9% with sulfonylurea, and 0.8% when combined with metformin and sulfonylurea. Byetta® was also studied in 233 patients uncontrolled on pioglitazone alone; decrease in A1C at 16 weeks was 0.8%.

Sitagliptin (Januvia®)

Sitagliptin (Januvia®) is the first in another new class of medications. Sitagliptin acts as an inhibitor of the enzyme dipeptidyl peptidase IV (DPP-4). This is the enzyme responsible for the degradation of GIP and GLP-1. By inhibiting the DPP-4 enzyme, the half life of endogenous GLP-1 is increased. Sitagliptin is approved as monotherapy or combination therapy with TZDs or metformin for the treatment of type 2 diabetes. Dosing for sitagliptin is simple; most patients receive 100 mg QD. However, for patients with renal insufficiency (CrCl between 30-50 mL/min) 50 mg QD is the maximum dose, and for patients with severe renal insufficiency (CrCl <30 mL/min) 25 mg QD is the maximum dose.

Unlike exenatide, this class of medication is available in an oral formulation and is generally weight neutral when used as monotherapy.

Adverse reactions seen in trials are mild and limited primarily to nasopharyngitis, upper respiratory tract infections, and headache. No major drug interactions have been identified.

To receive the monotherapy indication, sitagliptin was compared to placebo in an 18 week study enrolling 521 patients. A1C decreases of 0.6% and 0.48% respectively were detected. The authors concluded that sitagliptin was effective at improving glycemic control and was well tolerated in patients with type 2 diabetes who had inadequate glycemic control on diet and exercise alone.

Sitagliptin has also been used as an adjunct therapy in patients uncontrolled on pioglitazone alone. Sitagliptin plus pioglitazone resulted in an A1C decrease of 0.7% in a 24 week study enrolling 353 patients. Sitagliptin was not associated with more incidences of hypoglycemia than placebo.

Sitagliptin plus Metformin (Janumet®)

A combination product of sitagliptin and metformin (Janumet®) was approved in April 2007. It is indicated for patients that are not controlled on metformin or sitagliptin alone or for patients already taking metformin and sitagliptin as separate products. Janumet® is dosed BID, and is available as 50 mg sitagliptin + 500 mg metformin or 50 mg sitagliptin + 1000 mg metformin. Janumet® has the same contraindications and precautions as each of its components.

In a noninferiority trial, 1172 patients with type 2 diabetes not controlled on metformin alone were assigned to additional treatment with sitagliptin 100 mg QD or glipizide. Patients were followed for 52 weeks. A1C was decreased by 0.67% in both the sitagliptin and glipizide group, thereby confirming noninferiority. In this trial, body weight significantly decreased with sitagliptin by 1.5 kg and significantly increased with glipizide by 1.1 kg after 52 weeks.

Incretins Place in Therapy

Currently incretin therapy is not indicated as first line for patients with type 2 diabetes. Neither Byetta® nor Januvia® is mentioned in the ADA's treatment guideline for the management of type 2 diabetes. Metformin is still first line therapy, followed by insulin, sulfonylureas, or TZDs. The incretin class should be looked at as adjunct therapy. A1C decreases are not as significant with Byetta and Januvia as with other classes of antidiabetic agents. Also, Byetta® is associated with extensive nausea upon initiation of therapy, but patients typically develop tolerance as therapy continues. Byetta® is also only available as a BID injection.

Despite only modest decreases in A1C, Januvia® is generally well tolerated and available orally. Byetta® is typically associated with significant weight loss, while Januvia® is weight neutral or has small effects on weight loss. Weight gain is a significant issue with most of the other classes of antidiabetic agents. In patients with type 2 diabetes, any medication that could assist with weight loss or at least not cause weight gain should be looked on favorably. Since the incretin system is glucose dependent, this class of medications is not typically associated with less hypoglycemia. This could be beneficial for patients with hypoglycemic unawareness. The pros and cons of incretin therapy should be carefully weighed for each patient, but the incretin system represents a novel adjunct therapy for patients with uncontrolled type 2 diabetes.

References available upon request.

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