

## Medicaid Eligibility Card Changes

### All Providers

Louisiana Medicaid has stopped issuing the pink Take Charge Medicaid eligibility card (MEC) for new Take Charge enrollees. Effective August 1, 2011, Louisiana Medicaid began issuing only white MECs to all Medicaid enrollees regardless of the Medicaid program or scope of the benefits package. Although only the white MEC is being issued, providers should continue to accept the pink Take Charge card for current Take Charge enrollees.

Providers are reminded to always verify Medicaid eligibility and coverage limitations or restrictions prior to providing services. Eligibility can be verified by either logging in to the Louisiana Medicaid Provider Support Center at [www.lamedicaid.com](http://www.lamedicaid.com) or calling the Recipient Eligibility Verification System (REVS) at 1-800-776-6323.

[lamedicaid.com](http://www.lamedicaid.com) or calling the Recipient Eligibility Verification System (REVS) at 1-800-776-6323.



## TABLE OF CONTENTS

Medicaid Eligibility Card Changes	1
Licensing Standards for Home and Community-Based Services Published	1
Implementation of the Community Choices Waiver Delayed	2
National Correct Coding Initiative: Practitioner, Ambulatory Surgical Center and Outpatient Hospital Services Procedure-to-Procedure Edits 2	
Online Medicaid Provider Manual Chapters	2
Avoid Hiring or Employing Excluded Individuals	3
Remittance Advice Corner	3-4
Pharmacotherapeutic Management of Gout with an Update on Colcrys	4-6
References	7

## Licensing Standards for Home and Community-Based Services Published

### HCBS Providers

Effective July 1, 2011, new licensing standards published in the *Louisiana Register* on June 20, 2011 created a single Home and Community-Based Services (HCBS) license. The new standards merge the following services into one license:

- Personal Care Attendant (PCA),
- Supervised Independent Living (SIL) including the Shared Living Conversion services in a waiver home,
- Respite,
- Adult Day Care,
- Substitute Family Care,
- Supported Employment, and
- Family Support.

As existing licenses are renewed, a single HCBS license will be issued rather than a separate license for each provider type. Health Standards will begin utilizing a new HCBS license application for renewals in the near future. Additionally, renewal fees for the new license have changed in accordance with Louisiana R.S. 40:2120.4. The new fees are:

- Six hundred dollars per year for the base license for HCBS providers who provide in-home services,
- An additional \$200 dollars per year for HCBS providers who provide adult day care services, and
- An additional \$200 dollars per year for HCBS providers who provide out-of-home respite care.

Many of the requirements in the Standards of participation for Waiver Services published September 20, 2003 are now included in the HCBS licensing standards. Therefore, with the publication of the new licensing standards, the Office of Aging and Adult Services (OAAS) and the Office of Citizens with Developmental Disabilities (OCDD) are proposing that the Standards of Participation for Waiver Services be repealed. OAAS and OCDD will notify providers of the outcome of this proposal.

Provider training on the new licensing standards will be offered in the upcoming months. Providers will be notified once these plans are finalized.

In order to allow providers time to make this transition, **Health Standards will not begin enforcing compliance with these requirements until October 1, 2011.**

A copy of the new licensing standards can be viewed on the Office of State Register website at <http://www.doa.louisiana.gov/OSR/reg/reg2011.htm> and a copy of Louisiana R.S. 40:2120.4 can be viewed at <http://www.legis.state.la.us/lss/lss.asp?doc=321362>. Questions regarding these changes may be directed to Health Standards at (225) 342-0138.



## Implementation of the Community Choices Waiver Delayed

### HCBS Providers

The Office of Aging and Adult Services (OAAS) is announcing the delay in implementation of the new Community Choices Waiver. The Community Choice Waiver which will replace the Elderly and Disabled Adult Waiver is being delayed until October 1, 2011 to allow the necessary systems changes to be finalized and tested.

OAAS will take this opportunity to provide additional information to stakeholders and providers about the new waiver and to offer training to contractors and support coordinators.

Providers interested in enrolling as a provider of the new waiver services are encouraged to

contact the Molina's Provider Enrollment Unit at (225) 216-6370 for information.

Information regarding the Community Choices Waiver will be posted to the OAAS website at <http://new.dhh.louisiana.gov/index.cfm/subhome/12/n/7> as it becomes available.

## National Correct Coding Initiative: Practitioner, Ambulatory Surgical Center and Outpatient Hospital Services Procedure-to-Procedure Edits

### All Providers

The Affordable Care Act of 2010 requires that states incorporate National Correct Coding Initiative (NCCI) edits and methodologies for claims filed on or after April 1, 2011 for dates of service on or after October 1, 2010. Effective for claims processed on the remittance date of June 21, 2011, Louisiana Medicaid is applying the mandatory procedure-to-procedure editing methodologies that are components of the NCCI editing. These will apply to practitioner, ambulatory surgical center (ASC) and outpatient hospital services. (Note: Practitioner includes those licensed medical professionals who submit claims to Medicaid using Healthcare Common Procedural Coding System (HCPCS)/Current Procedural Terminology (CPT) codes.)

Procedure-to-procedure edits are defined as pairs of HCPCS/CPT codes that should not be reported together. These NCCI edits are applied to service performed by the same provider for the same recipient on the same date

of service. When appropriate, modifiers may be applied to further describe the clinical scenario. Louisiana Medicaid's claims processing system has been updated to accept all NCCI-associated modifiers. Providers may **NOT** bill recipients for services denied by NCCI edits.

Providers could expect to see denials on procedures that may have previously paid when billed in the same manner. For NCCI edits, the decision on which procedure code of a code pair is payable was determined by the Centers of Medicare and Medicaid Services (CMS). CMS updates these edits quarterly. New edit messages that pertain specifically to NCCI edits have been added. Currently these are:

- 731 – CCI: Procedure incidental to another current procedure,
- 759 – CCI: Procedure incident to a procedure in history,

- 982 – CCI: History procedure incidental to current-history voided,
- 984 – CCI: Procedure mutually exclusive to another current procedure,
- 989 – CCI: Procedure mutually exclusive to procedure in history,
- 992 – CCI: History procedure mutually exclusive to current-history voided.

The NCCI methodologies for the medically unlikely edits (MUE) for units of service will be implemented at a future date. These edits will also include durable medical equipment suppliers' claims.

For additional information, please refer to prior NCCI notices dated March 15, 2011 and September 23, 2010 on the Medicaid website at [www.lamedicaid.com](http://www.lamedicaid.com). Providers are also encouraged to access information on the CMS website at [www.cms.gov](http://www.cms.gov) under the Medicaid NCCI link.

## Online Medicaid Provider Manual Chapters

### All Providers

The following Medicaid Provider Manual Chapters are available on the Louisiana Medicaid website at [www.lamedicaid.com](http://www.lamedicaid.com) under the "Provider Manual" link.

- Administrative Claiming
- Adult Day Health Care Waiver
- Ambulatory Surgical Centers
- American Indian 638 Clinics
- Children's Choice Waiver
- Dental
- Durable Medical Equipment
- Elderly and Disabled Adult Waiver
- Family Planning Clinics
- Family Planning Waiver (Take Charge)
- Federally Qualified Health Centers
- General Information and Administration
- Home Health
- Hospitals
- ICF/DD
- Medical Transportation
- Mental Health Clinics
- Mental Health Rehabilitation
- Multi-Systemic Therapy
- New Opportunities Waiver (NOW)
- Personal Care Services
- Pharmacy
- Psychological Behavioral Services
- Rural Health Clinics
- Supports Waiver
- Vision (Eye Wear)

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

## Avoid Hiring or Employing Excluded Individuals

### All Providers

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 is an employee or contractor, 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.

## Remittance Advice Corner

### All Providers

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

#### Attention Inpatient Acute Hospital Providers Change in Retrospective Review Process

In November of 2010 DHH changed the requirements for the retrospective review process for Acute Inpatient Hospital Providers. Since this time, DHH has monitored this process and listened to the suggestions and concerns of the hospital providers. Beginning August 1, 2011, a new retrospective review process will be implemented. Please visit the Medicaid website at [www.lamedicaid.com](http://www.lamedicaid.com) to review the amended process. Please note that this new process only applies to Acute Inpatient Hospitals and does not apply to Psychiatric, LTAC or Rehab Hospitals.

#### Attention All Ordering and Rendering Providers of High-Tech Radiology Services Radiology Utilization management (RUM)

Louisiana Medicaid has identified an issue related to the reimbursement of claims for Radiologic services, whereby claims were paid without an approved

Prior Authorization on file. We have identified and corrected the logic that allowed these claims to pay and have identified those claims paid in error. These are claims that were paid against a valid Prior Authorization, but the specific line for the procedure code was either denied or withdrawn, but the claim still paid. The claims that were paid in error will be voided on the 07/05/11 RA. If you have any billing or policy questions, please contact Provider Relations at (800) 473-2783 or (225) 924-5040.

#### Attention Providers of Prenatal and Pediatric Care Services

Louisiana Medicaid reminds providers of the Medicaid Prenatal and Preventive Pediatric Care Pay and Chase policy, as published in the *2006 Louisiana Medicaid Basic Services Provider Training*, page 40. This policy addresses certain prenatal and pediatric preventive care services, including immunizations (see bullet #2 of the policy), when the Medicaid enrollee also has a private health insurance carrier.

Providers accepting primary health insurance and Medicaid as secondary coverage for a Medicaid recipient should follow the Pay and Chase policy for all services identified in the policy. If providers

choose not to follow the Pay and Chase policy for services included in this policy, the recipient cannot be billed for Medicaid covered services. Example: A child requires a Medicaid covered childhood immunization(s) and has both private health insurance as well as Medicaid as secondary coverage. The Medicaid provider should use vaccines obtained from the Vaccines for Children (VFC) program to immunize the child and bill Medicaid directly. If the provider does not follow this policy and utilizes privately purchased vaccines, and if the private insurance carrier denies the immunization claim, Medicaid will not reimburse providers for the vaccine serum used and the provider cannot bill the recipient for the vaccine nor for the administration of the vaccine.

If a provider elects to not accept a recipient's Medicaid as secondary coverage, Louisiana Medicaid encourages providers to obtain signed documentation, prior to services being rendered, indicating the Medicaid recipient was made aware that the provider was not accepting Medicaid as secondary coverage, and that the recipient could be responsible for payment of services not covered by the private insurance.

*Continued on page 4*

## Remittance Advice Corner

Continued from page 3

### All Providers

Contact Molina Medicaid Solutions Provider Relations at (800) 473-2783 or (225) 924-5040 should you have any questions.

### Attention Professional Service Providers: Physiatrists Managing Intrathecal Baclofen Therapy

Effective with date of service August 1, 2009, Louisiana Medicaid reimburses physiatrists for intrathecal baclofen pump management. Services that may be provided by a physiatrist include pump analysis, programming, refill and maintenance. Providers are encouraged to refer to the *Current Procedural Terminology* manual for instructions on how to bill for these services.

Please contact the Molina Provider Relations Unit at (800) 473-2783 or (225) 924-5040 with questions concerning this issue.

## Louisiana Drug Utilization Review (LADUR) Education

### Pharmacotherapeutic Management of Gout with an Update on Colcris®

Kristen Pate, Pharm. D.  
Clinical Assistant Professor  
University of Louisiana at Monroe  
College of Pharmacy

#### Introduction

In the United States, an estimated 6.1 million adults have had gout. Gout is more common in the elderly, and men are more likely than women to have gout; however, due to the uricosuric effects of estrogen, gout becomes more prevalent as women age and estrogen levels decrease. The following can contribute to an increased risk of gout: certain medications, various disease states, genetic factors, and an increased intake of dietary purines, particularly meats and seafood, and other foods and drinks, such as fructose, soft drinks, and ethanol, especially beer and spirits. The overall incidence and prevalence of gout is likely rising as a result of dietary habits, a higher number of obese individuals, and an aging population.<sup>1</sup> Although the pathogenesis of gout is fairly well understood, it is still often misdiagnosed, diagnosed late, or not treated properly. A thorough understanding of the proper treatment of gout, including information regarding the recent changes to colchicine availability, will allow practitioners to better care for patients affected by this disease.<sup>2,3</sup>

#### Pathophysiology

Gout is a type of inflammatory arthritis that is caused when monosodium urate crystals are deposited in the synovial fluid of joints and other tissues. Due to the fact that humans do not produce uricase, humans are not capable of converting urate to the soluble allantoin during

purine metabolism. Deposition of urate crystals can occur as a result of hyperuricemia, defined as a serum uric acid level of 6.8 mg/dL or greater. When serum urate levels reach this point, urate solubility is limited at physiologic temperature and pH.<sup>1</sup> Acute gout attacks result from the deposition of monosodium urate crystals into joints, causing inflammation.<sup>4</sup> Hyperuricemia can be a result of the overproduction of urate or the under excretion of urate, and pharmacologic therapy is used to target each of these mechanisms. Hyperuricemia alone does not always lead to gout.<sup>1</sup>

#### Clinical Presentation

There are two clinical phases of gout. During the first phase, patients have intermittent acute gout attacks that will typically spontaneously resolve in 7 to 10 days; between attacks the patients are free of symptoms and pain. Acute attacks are a result of hyperuricemia, causing the precipitation of monosodium urate crystals. If this clinical phase of gout is not treated appropriately and urate levels are not controlled, it can progress to the second clinical phase of gout, chronic tophaceous gout. In chronic tophaceous gout, patients often experience polyarticular attacks, symptoms between attacks, and the deposition of crystals in soft tissues or joints. Diagnosis of gout is highly likely if a patient presents with rapid development of severe pain and redness and swelling of a joint commonly affected by gout, such as the first metatarsophalangeal joint.<sup>1</sup> Clinical presentation is very important in the diagnosis of gout, but serum uric acid levels, the presence of uric acid crystals in synovial fluid, radiographic evidence, and associated risk factors and comorbidities should also be assessed.<sup>1,2</sup>

#### Treatment

Management of gout should combine a combination of non-pharmacologic and pharmacologic approaches. Treatment should take into consideration the clinical phase of gout, the number of acute gout attacks, the serum uric acid level, and risk factors and comorbidities.<sup>5</sup> Pharmacologic therapy is aimed at treating an acute gout attack or lowering serum uric acid levels.

#### Acute Treatment

Non-steroidal anti-inflammatory drugs (NSAIDs) and oral colchicine are first-line agents for the treatment of acute gout attacks. Studies have shown that they are both effective in managing pain and inflammation in acute gout, but no studies have directly compared NSAIDs and colchicine. Different NSAIDs have been directly compared to one another for the treatment of acute gout, and it appears that they have similar efficacy. Although both colchicine and NSAIDs are considered effective treatment options, they each have concerns regarding adverse effects. For example, colchicine can cause diarrhea, nausea, and vomiting, especially with high doses. NSAIDs' potential adverse effects include gastrointestinal bleeding. In patients with severe mono-articular gout or those with contraindications to colchicine and NSAIDs, intra-articular injection of long-acting steroids is a safe and effective treatment option for acute gout. Intra-articular steroid injections, along with intra-articular aspiration, are commonly used in practice but have not been studied in randomized trials. Systemic steroids are also used, but are most useful in patients

with severe polyarticular attacks or for attacks in sites in which aspiration or intra-articular injection cannot be easily performed.<sup>5</sup> All of the medications indicated for use in acute gout attacks act by exerting anti-inflammatory action,

through their own individual mechanisms.<sup>6,7,8</sup> The intense inflammatory response of an acute gout attack may take 7-10 days of treatment to resolve. Often, higher doses of anti-inflammatory drugs are given for the first few days until the

symptoms and pain begin to improve. If a patient is taking urate-lowering therapy, it should not be interrupted during an acute attack.<sup>1</sup>

### Pharmacologic Treatment Options for Management of Acute Gout Attacks<sup>1,7,8,9</sup>

Drug	Dosing	Comments
Colchicine	1.2 mg at the first sign of gout flare, then 0.6 mg 1 hour later	Monitor for adverse effects in patients with CrCl 30-80 mL/minute; if CrCl is < 30 mL/minute, acute treatment should not be repeated more than once every 2 weeks; patients on dialysis should receive a single 0.6 mg dose for acute treatment
NSAIDs		
Indomethacin	50 mg 3 times daily until pain is tolerable	Decreased dose should be given until acute therapy is complete
Naproxen	750 mg initial dose, followed by 250 mg every 8 hours until attack subsides	
Oral glucocorticoids		
Prednisolone	30-35 mg daily for 5 days	

\*Above information is not all inclusive regarding treatment options or specific drug recommendations

### Hyperuricemia Treatment

Hyperuricemia treatment should be used in patients with recurrent acute attacks, tophi, or radiographic changes consistent with gout. Urate-lowering therapy with a goal serum uric acid of less than 6 mg/dL will help promote crystal dissolution and prevent crystal formation. Clinical decisions regarding when to start urate-lowering therapy must be patient specific and take into account the risks versus benefits.<sup>5</sup> Urate-lowering drugs should not be initiated during an acute gout attack; however, if a patient has an acute attack while taking urate-lowering drugs, the urate-lowering drug should not be discontinued.<sup>6</sup>

Allopurinol, a xanthine oxidase inhibitor, is an appropriate first-line treatment option for urate-lowering therapy.<sup>5</sup> Xanthine oxidase inhibitors act in the catabolism of purines by inhibiting xanthine oxidase, the enzyme responsible for the conversion of hypoxanthine and xanthine to uric acid.<sup>10</sup> An initial dose of 100 mg of allopurinol daily, increased weekly by 100 mg to achieve a serum uric acid less than 6 mg/dL, can reduce the incidence of allopurinol toxicity and acute gout attacks. The dose should not exceed 800 mg daily, and doses greater than 300 mg should be given in divided doses.<sup>5,10</sup> The dose of allopurinol should be adjusted in patients with renal impairment due to the accumulation of allopurinol during renal failure.<sup>10</sup> If a patient develops toxicity to allopurinol, especially hypersensitivity,

treatment alternatives include other xanthine oxidase inhibitors or uricosuric agents. If alternative agents fail and the patient has only a mild hypersensitivity reaction, allopurinol desensitization is an option.<sup>5</sup>

Febuxostat (Uloric®), a selective nonpurine xanthine oxidase inhibitor, was approved for use in 2009, and it is the only other xanthine oxidase inhibitor available in the United States.<sup>11</sup> Febuxostat is particularly useful in patients who cannot tolerate allopurinol.<sup>4,11</sup> The recommended starting dose is 40 mg once daily. After 2 weeks of therapy, if serum uric acid is not less than 6 mg/dL, the dose can be increased to 80 mg once daily.<sup>12</sup> Dosing adjustments are not necessary in patients with mild to moderate renal impairment (creatinine clearance 30-89 mL/minute), but it has not been adequately studied in patients with severe renal impairment.<sup>11,12</sup> Periodic liver enzyme monitoring is recommended due to observed elevations in transaminases in patients taking febuxostat. The use of febuxostat is contraindicated in patients currently taking azathioprine or mercaptopurine, and it should be used with caution in patients taking theophylline.<sup>12</sup>

Uricosuric agents are an alternative treatment option for patients who under excrete uric acid.<sup>1</sup> They inhibit the tubular reabsorption of urate, which increases uric acid excretion and decreases serum uric acid. When initiating treatment with probenecid, the dose should be started at 250 mg

twice daily for 1 week, then increased to 500 mg twice daily. The dose may be increased by 500 mg daily every 4 weeks if necessary, with the total daily dose typically not exceeding 2000 mg. Probenecid may not be effective in patients with a glomerular filtration rate of 30 mL/minute or less.<sup>13</sup>

In September 2010, the United States Food and Drug Administration (FDA) approved pegloticase (Krystexxa™), the first PEGylated uric acid specific enzyme (uricase) that metabolizes uric acid into soluble allantoin, which can be excreted by the kidneys.<sup>14,15</sup> It is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. It is not recommended for the treatment of asymptomatic hyperuricemia. Pegloticase 8 mg should be given as an intravenous infusion every 2 weeks. Anaphylaxis and infusion reactions have been reported with the administration of pegloticase. Thus, it should be infused in a healthcare setting with trained professionals, patients should be premedicated with antihistamines and corticosteroids, and patients should be observed for approximately 1 hour following the infusion. Pegloticase is contraindicated in patients with G6PD deficiency due to the risk of hemolysis and methemoglobinemia, and caution should be used in patients with heart failure, as in clinical trials some patients experienced heart failure exacerbations.<sup>15</sup>

Continued on page 6

## Louisiana Drug Utilization Review (LADUR) Education

Continued from page 5

Pharmacologic Treatment Options for Management of Hyperuricemia <sup>1,10,12,13,15</sup>		
Drug	Dosing	Comments
Xanthine Oxidase Inhibitors		
Allopurinol	Initial dose of 100 mg daily, increased weekly by 100 mg to achieve a serum uric acid < 6 mg/dL	Dose should not exceed 800 mg daily; doses greater than 300 mg should be given in divided doses; dosage adjustment required in renal impairment
Febuxostat	40 mg once daily; increase to 80 mg once daily after 2 weeks if serum uric acid not < 6 mg/dL	No adjustment necessary in mild to moderate renal impairment
Uricosuric agent		
Probenecid	250 mg twice daily for one week, then 500 mg twice daily; can increase every 4 weeks by 500 mg if necessary	Maximum daily doses typically do not exceed 2000 mg; may not be effective if CrCl is < 30 mL/min; adequate hydration required
Uricase		
Pegloticase	8 mg IV infusion every 2 weeks	Must be administered in healthcare setting; premedication required; observe patient following infusion

\*Above information is not all inclusive regarding treatment options or specific drug recommendations

### Flare Prophylaxis During Initiation of Urate-Lowering Therapy

With initiation and dosage increase antihyperuricemic drugs are capable of inducing an acute gout attack by causing urate mobilization due to changing serum uric acid levels.<sup>5,11,15</sup> Low-dose colchicine (0.6 mg once or twice daily) or NSAIDs can provide prophylaxis against these attacks during the first few months of urate-lowering therapy, although there is less evidence with the use of NSAIDs for this purpose.<sup>15</sup> Prophylaxis should be continued for 6 months and until tophi, which is the deposition of crystals, resolve.<sup>1</sup>

### Non-pharmacologic Treatment

Treatment of patients with gout should include patient education regarding both pharmacologic and non-pharmacologic therapy. Non-pharmacologic recommendations should include advising patients against consuming a diet high in animal purines, encouraging weight loss in obese patients, and education regarding limiting alcohol consumption, especially beer. Treatment of comorbidities, especially hypertension, diabetes, and hyperlipidemia, should also be addressed in the management of gout.<sup>5</sup>

### New Colchicine Product – Colcrys®

Oral colchicine products have been available to patients for decades. However, none of these products ever received formal FDA approval, which is required of all prescription medications. Additionally, these products were being marketed without official regulation by the FDA. In September 2010, the FDA ordered that all unapproved colchicine products should not be manufactured, distributed, or marketed. Currently, the only FDA-approved colchicine product is marketed under the brand name of Colcrys®, which was approved in 2009. Colcrys® prescribing information contains recommendations regarding dosing, safety, and drug interactions that are not contained within the prescribing information of unapproved colchicine products.<sup>3</sup> Increased concentrations of Colcrys® are likely if it is administered with P-glycoprotein inhibitors or cytochrome P450 3A4 inhibitors, including grapefruit juice. Prescribing information contains tables with recommendations regarding the administration of Colcrys® with specific P-glycoprotein inhibitors, cytochrome P450 inhibitors, and other drugs that can potentially increase the concentration of Colcrys®.<sup>7</sup> As part of the approval process, the manufacturer of Colcrys® submitted data from a clinical trial evaluating the safety and efficacy of low-dose colchicine compared to the traditional high-dose regimen. This trial revealed that the traditional high-

dose regimen increased the risk of adverse events, especially gastrointestinal side effects, without an advantage in regards to efficacy over low-dose regimens.<sup>16,17</sup> Colcrys® is approved for the prophylaxis and treatment of gout flares in adults. Recommended dosing for treatment of gout flares is 1.2 mg (2 tablets) at the first sign of a gout flare, followed by 0.6 mg (1 tablet) 1 hour later. For prophylaxis of gout flares, Colcrys® 0.6 mg can be given once or twice daily.<sup>7</sup> The manufacturer of Colcrys® has established a patient assistance program and a co-pay assistance program in order to improve patient access. More information regarding these programs can be found on the Colcrys® website ([www.colcrys.com](http://www.colcrys.com)).<sup>18</sup>

### Conclusion

Due to the high prevalence of gout in the United States, it is important that healthcare professionals adequately diagnose and treat this disease state.<sup>5,11</sup> First-line treatment for acute gout includes colchicine and NSAIDs, and allopurinol is recommended as first-line treatment for patients who require urate lowering therapy.<sup>5</sup> Newly available pharmacologic options for the treatment of gout make it a more manageable and treatable disease than in the past. These new options provide an alternative for those patients in whom traditional therapy is intolerable or not efficacious.<sup>6,11</sup>

## References

1. Neogi T. Gout. *NEJM*. 2011;364(5): 443-452.
2. Zhang W, et al. EULAR evidence based recommendations for gout. Part I: Diagnosis. Report of a task force of the standing committee for international clinical studies including therapeutics (ESCSIT). *Ann Rheum Dis*. 2006;65:1301-1311.
3. U.S. Food and Drug Administration. FDA orders halt to marketing of unapproved single-ingredient oral colchicine. September 30, 2010. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227796.htm>. Accessed June 2, 2011.
4. Gray CL, Walters-Smith NE. Febuxostat for the treatment of chronic gout. *Am J Health-Syst Pharm*. 2011;68: 389-398.
5. Zhang W, et al. EULAR evidence based recommendations for gout. Part II: Management. Report of a task force of the EULAR Standing Committee for international Clinical Studies Including Therapeutics (ESCSIT). *Ann Rheum Dis*. 2006;65:1312-1324.
6. Cannella AC, Mikuls TR. Understanding treatments for gout. *The American Journal of Managed Care*. 2005;11(15):S451-458.
7. Colcrys [package insert]. Philadelphia, PA: Mutual Pharmaceutical Company, Inc; 2010.
8. Indomethacin [package insert]. Princeton, NJ: Sandoz, Inc.; 2007.
9. Naproxen [package insert]. Corona, CA: Watson Laboratories, Inc.; 2007.
10. Allopurinol [package insert]. Memphis, TN: Northstar Rx LLC; 2009.
11. Reinders MK, Jansen T. New advances in the treatment of gout: a review of pegloticase. *Therapeutics and Clinical Risk Management*. 2010;6:543-550.
12. Uloric [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2011.
13. Probenecid [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc; 2006.
14. United States Food and Drug Administration. FDA approves new drug for gout. September 2010. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225810.htm>. Accessed June 14, 2011.
15. Krystexxa [package insert]. New Brunswick, NJ: Savient Pharmaceuticals, Inc.; 2010.
16. United States Food and Drug Administration. Information for healthcare professionals: New safety information for colchicine (marketed as Colcrys). <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm174315.htm>. Accessed June 3, 2011.
17. Terkeltaub RA, et al. High versus low dosing of oral colchicine for early acute gout flare: twenty-four-hour outcome of the first multicenter, randomized, double-blind, parallel-group, dose-comparison colchicine study. *Arthritis and Rheumatism*. 2010;62(4):1060-1068.
18. Colcrys website. Patient Assistance Initiatives. <http://colcrys.com/healthcare-professional/patient-assistance-program.htm>. Accessed June 15, 2011.



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

7553MMS0811

***For information or assistance, call us!***

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