

the Remedi Pulse



A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

OCTOBER 2014

Nov 1: Trick or Treat?

Prepared by: David Lasher
Chief Information Officer

This year, it is the day after Halloween that might be scary. On November 1, prescribers, pharmacies, and facilities in the long-term care industry (LTC) must cease the transmission of electronic medication orders via the HL7 and e-fax methods that predominate today. Per CMS regulations, prescribers, pharmacies, and facilities – and the technology vendors on whom they rely – must switch to a new transmission method, NCPDP SCRIPT 10.6 (SCRIPT), for medication orders to remain eligible for Medicare Part D reimbursement. Those who cannot transmit their electronic orders via SCRIPT on November 1, will need to revert to manual methods of transmission in order to be eligible for reimbursement.

If prescriber, pharmacy, facility, and technology vendor have not all made successful transition to SCRIPT by the deadline, the fulfillment of patient prescriptions could be delayed or disrupted. This article summarizes steps that Remedi is taking in order to prevent that scary prospect from actually coming to be.

What is SCRIPT?

SCRIPT, like HL7, defines a structure by which the data relating to an electronic order is organized for transmission and processing. SCRIPT, unlike HL7, is broadly used outside of LTC. The CMS goal with the November 1 deadline is to bring LTC into conformance with standards that prevail in the rest of the healthcare services industry. To learn more about both SCRIPT and NCPDP (the latter being the body that oversees the standard), please see: <http://www.ncdp.org> or <http://www.cms.gov/eprescribing>.

What will be the Impact on Remedi?

Whereas all HL7 and e-fax (i.e., computer-generated-fax or CGF) systems must be disabled as of November 1, our customers and their EHR vendors need to be ready either for transition to SCRIPT or for reversion to manual fax for transmission of medication orders to us. And since relatively few EHR vendors had deployed SCRIPT interfaces that were certified for production operation even as of

continue, pg 4

“On November 1, prescribers, pharmacies and facilities in the long-term care industry must cease the transmission of electronic medication orders via the HL7 and e-fax methods that predominate today.”

FOR MORE INFORMATION

RemediRX.com

EDITORIAL STAFF

JENNIFER HARDESTY PharmD., FASCP
Chief Clinical Officer,
Corporate Compliance Officer
Jennifer.Hardesty@RemediRX.com

ROB SHULMAN BS, RPh, CGP, FASCP
Director of Consultant Pharmacy Services
Rob.Shulman@RemediRX.com

REBECCA OGDEN BSN, RN, CRNI
Corporate Account Manager
Rebecca.Ogden@RemediRX.com

Please do not hesitate to contact your Remedi Consultant Pharmacist or Account Manager if you have any questions or concerns.

New Drug Update: Brintellix® (vortioxetine):

For Major Depressive Disorder

Prepared by: Janelle Massaro, PharmD, Clinical Consultant
Pharmacist

Depression affects approximately 1 in 10 Americans, nearly 14 million people, according to a CDC survey conducted in 2010 with 6.6% of those experiencing Major Depressive Disorder (MDD). Depression is defined as per DSM-IV criteria (2) as: depressed mood for most of the day, decreased interest and/or pleasure in activities, unintentional weight loss or gain, excess sleep or lack of which may lead to loss of energy or fatigue, feelings of worthlessness or guilt, agitation, and recurrent thoughts of death. These symptoms may not affect every person and some may be more prominent than in others. To be clinically diagnosed as having depression, 5 of the above symptoms are present for at least 2 continuous weeks. Depression may be seen through a variety of symptoms with multiple forms of depression such as; adjustment disorder with depression, bereavement, bipolar (mania and depression), and dysthymic disorder (continuous depression for long periods of time). Many drugs are available to treat MDD and its subsequent disorders utilizing Serotonin, Norepinephrine and Dopamine pathways in the CNS. Brintellix® (vortioxetine) is one of the newest of these medications acting on the serotonergic pathway in multiple forms.

Brintellix, approved in September 2013, has a unique mechanism of action as a serotonin reuptake inhibitor (SSRI), serotonin antagonism on 5-HT₃ and 5-HT_{1A} agonist. These actions may increase serotonin leading to improvement in mood, sleep and social ability. Positive effects of this medication may be seen as early as 2 weeks with maximum benefit seen around 6-8 weeks, as with most anti-depressant medications. Brintellix® can be taken once daily, as either 10mg or 20mg-without regard to food, due to its extended half-life of up to 66 hours. This will also allow for easier titration off the medication if needed. The most common side effects seen with taking Brintellix are nausea, vomiting, and constipation with no significant changes in weight. This medication, as with other

antidepressant medications, should be only given to those 18 years and older as the risk for suicidal thoughts may be increased with younger age.

In summary, if one antidepressant is not effective, another drug in the same or similar class may be effective. There are many options available for the treatment of MDD with varying mechanisms that may benefit multiple symptoms. Please consult with your physician or your Remedi Clinical Consultant Pharmacist for any questions on depression or the available treatment options.

References

CDC. Current Depression Among Adults --- United States, 2006 and 2008. MMWR 2010;59(38):1229-1235.

Diagnostic and Statistical Manual of Mental Disorders, Text Revision. 4th Edition, Appendix D (DSM-IV-TR; APA, 2000).

Brintellix® Package Insert; Takeda Pharmaceuticals America, Inc. September 2013.

Depression affects approximately 1 in 10 Americans, nearly 14 million people, according to a CDC survey conducted in 2010 with 6.6% of those experiencing Major Depressive Disorder (MDD). Many drugs are available to treat MDD and its subsequent disorders utilizing Serotonin, Norepinephrine and Dopamine pathways in the CNS. Brintellix® (vortioxetine) is one of the newest of these medications acting on the serotonergic pathway in multiple forms.

Gout

Prepared by: Rebekah Criner, PharmD, CGP, Clinical Consultant Pharmacist

“Ouch! That hurts. Don’t touch my toe.” Mr. Smith tells his nurse as she adjusts his sheets. She takes a look at his big toe and sees that it looks red and swollen. “I’m sorry, Mr. Smith. That looks painful. I’ll call the doctor and see what we can do for you.” You explain to the doctor, and she states that she thinks it is gout. She orders an Indocin (an NSAID), and Colchicine. She also wants a uric acid level drawn.

What is gout? How can I help my patients with it stay pain free? What medications are available to treat it?

Gout is the most common cause of inflammatory arthritis in adults in the United States. It affects small joints, most commonly the big toes, as well as fingers and large joints like ankles, knees, hips, wrists, elbows, and shoulders. It is painful and is caused by the precipitation of monosodium urate crystals. When a uric acid level is drawn the goal is to have a level < 6mg/dL.

Most acute gout attacks can be treated with NSAIDs, steroids, or Colchicine. A patient’s renal function must be evaluated when using NSAIDs (<50mL/min) and Colchicine (<30mL/min) and adjusted accordingly. NSAIDs may be contraindicated in patients with a history of GI bleeding and heart failure. Some prescribers may still order NSAIDs since the duration is just a short time period. The dosage of Colchicine can be limiting due to adverse effects of diarrhea and GI upset. Steroids have a multitude of side effects, as well, such as increased blood glucose and blood pressure, mood changes, increased appetite, fluid retention, and insomnia.

How do you differentiate between gout attack and arthritis attack? There are no major differences between these two painful issues. The definitive diagnosis of gout would be based on an elevated uric acid level (> 0.6gm/dl).

First line therapy for **prevention** of gout attacks is Allopurinol and Uloric. Allopurinol is significantly less expensive, but has no

Drug Class/Drug Name	Dosage	Dosage Adjustments	Side Effects
Acute Treatments			
NSAIDs: Indomethacin Naproxen	50 mg 3-4x/day x 3 days, then 50 mg BID x 4-7 days 750-1000 mg/day x 3 days, then 500-750 mg/day x 4-7 days		GI bleed
Colchicine (Colcrys)	1.2 mg loading dose, then 0.6 mg 1hr later Old dosing: 1.2 mg initially, then 0.6 mg q1hr until flare resolution or until GI toxicity occurs	CI with CYP3A4 inhibitors such as Biaxin, Verapamil, Diltiazem, and Cyclosporine Avoid grapefruit juice	GI upset, diarrhea
Steroids: Prednisone, Medrol dose pack	20-60 mg/day x 5-7 days UAD on package		Incr BP, Incr BG, mood swings, insomnia
Chronic Treatment/ Prophylaxis			
Xanthine Oxidase inhibitors (Allopurinol and Uloric)	Allopurinol 100 mg QD and increase every few weeks until uric acid level is < 6 mg/dL; Max dose 800 mg/day Uloric 40 mg QD, Can be increased to 80 mg/day	Max 200 mg/day in CrCl ≤20 mL/min Caution when CrCl < 30 mL/min	GI intolerance, rash
Probenecid	250 mg BID x 7 days, then 500 mg BID	CI in CrCl < 50 mL/min	GI upset
Colchicine (Colcrys)	0.6 mg QD or BID	CrCl < 30 mL/min = 0.3 mg QD Dialysis: 0.3 mg 2xweekly	GI upset, diarrhea

role in the treatment of an acute attack.

In order to reduce the risk of gout attacks, it is important to encourage weight loss if overweight, exercise, hydration, and smoking cessation. Avoid certain foods such as organ meats, high fructose corn syrup and other sugary drinks and foods, salt

intake, and alcohol. Certain medications can increase the risk for a gout attack. These medications include: thiazide diuretics, salicylates, Cyclosporine, Levodopa.

Luckily, our resident responded well to the NSAID (Indocin) because the Colchicine

Nov. 1: Trick or Treat?

early September, we expect that at least some of our customers will need to revert to manual fax on November 1 in order to remain CMS compliant.

What is Remedi Doing?

Remedi has adopted a multi-prong approach to promote readiness for the November 1 deadline. We have engaged the NCPDP and CMS organizations to validate our understanding of the regulations. We are cooperating with the IT departments of 20 other LTC pharmacies to understand the technical implications of the new SCRIPT standard. We are working directly with EHR vendors and we are upgrading our internal software system to enable SCRIPT interfaces and workflow. We are updating our own My Remedi portal. And we are executing an education campaign with our customers.

Stay tuned for more as we move through September and October. And let not November 1st haunt your days.

Nurse of the Month



SHARON FRICKE, RN, MDS
Coordinator at Villa Angela Care
Center in Columbus, Ohio

CONGRATULATIONS TO Sharon Fricke, RN, MDS Coordinator at Villa Angela Care Center in Columbus, Ohio for being chosen as the Remedi “Nurse of the Month!” Sharon was nominated by Molly Brenner, Assistant Administrator at Villa Angela. Per Molly: “Sharon has been a RN for over 40 years and has worked at Villa Angela for 32 years. She has worked as an aide, floor nurse and in managerial positions. Sharon has shown her love for Villa Angela through excellent patient care, quality of work and dedication to our residents. She deserves to have a “spotlight” on her for all the years she has given Villa.”

Remedi acknowledges a “Nurse of the Month” in each of our newsletters. DONs/ADONs/LNHAs, NOW is the time for you to award the nurse(s) at your facility who exemplify excellence in nursing practice. The “Nurse of the Month” will also receive an award and a certificate of commendation from Remedi. Please submit the following information: nominated nurse’s name/title, facility name, state, years at facility, years of experience and why this nurse should be chosen, such as leadership abilities, clinical expertise, teamwork, professional and personal strengths.

Email your “Nurse of the Month nomination(s)” no later than the 30th of the month to Rebecca.Ogden@RemediRX.com Nurses Rock!!

Gout (cont’d)

required a prior authorization. Currently, the only form of Colchicine on hand is the brand name Colcris, which is significantly higher in cost than the generic Colchicine that was formerly available. The FDA withdrew it due to lack of proof of efficacy and safety. Keep this in mind when the doctor writes for Colchicine; Colcris is what will be dispensed by the pharmacy.

Your Remedi SeniorCare Consultant Pharmacist can answer more specific questions that you may have concerning treatment of gout. He or she may recommend monitoring of renal function or periodic uric acid levels and stop dates for acute drug treatment when warranted.

References

Khanna, Fitzgerald, Khanna, Bae, Singh, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 1: Systemic Nonpharmacologic and Pharmacologic Therapeutic Approaches to Hyperuricemia. Arthritis Care and Research. Volume 64, Number 10, October 2012, pp 1431-1446.

Khanna, Khanna, Fitzgerald, Singh, Bae, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Antiinflammatory Prophylaxis of Acute Gouty Arthritis. Arthritis Care and Research. Volume 64, Number 10, October 2012, pp 1447-1461.

www.pharmacistsletter.com – Management of Gout. November 2010, Volume 26.

www.pharmacistsletter.com – New Drug: Uloric (Febuxostat). April 2009, Volume 25.

www.pharmacistsletter.com – Comparison of Gout Therapies. December 2012.

www.pharmacistsletter.com – New Safety Information for Colchicine and the Approval of Colcris. September 2009, Volume 25.
www.GoutRx.com