

"Giving Voice to Those Seldom Heard"

December 2019

Dear Colleague:

Greetings from the Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD). This cover letter is to announce the Winter Alerts for 2019/2020 from the Medical Review Subcommittee:

Winter Alert 2019 - Hypothermia Alert - Frostbite Alert - NWS Wind Chill Chart

If you haven't already, please visit the OMHDD website to [subscribe to receive the Medical Alerts via E-mail](https://public.govdelivery.com/accounts/MNOMHDD/subscriber/new?qsp=CODE_RED) (https://public.govdelivery.com/accounts/MNOMHDD/subscriber/new?qsp=CODE_RED).

Death and Serious Injury Reporting Update

Reports of deaths and serious injuries can be faxed to the OMHDD at the following number:

Fax: 651-797-1950

It has come to our attention that this fax number only can receive faxes from digital (not analog) fax machines. If you are using an older (analog) fax machine and have difficulty faxing reports to the office, please use this number: 651-296-1021.

Beginning in early 2020, this office will be launching dedicated webforms to report Deaths and Serious Injuries online securely to the OMHDD. The links will be on the Office of Ombudsman website under "Reporting Death or Serious Injury." When they are available, we will send an announcement to all subscribers to the Medical Alerts. Instead of completing the Death Report or Serious Injury Report Forms by hand or on the OMHDD website and then printing it and faxing it to the Office, you will be able to access separate webforms for death reporting and for serious injury reporting. You still will be able to fax supporting documentation via the existing fax number, and you will be able to print a copy of the report submitted on the website for your records. More information will be coming soon!

If you have questions about reporting or need to contact our office, please call any of the following numbers:

Voice: 651-757-1800

Toll Free: 800-657-3506

TTY/Voice: Minnesota Relay Service 711

FDA MedWatch Updates have transitioned to FDA's Drug Safety Communications:

This office continues to recommend that providers, families and clients be aware of the FDA's Drug Safety Communications webpage, which provides updated and on-going information about warnings and alerts for medications. The FDA has released Drug Safety Communications for many medications, many of which are prescribed for clients of this Office. These medications include:

FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer - [9-13-2019]. The U.S. Food and Drug Administration (FDA) is warning that Ibrance (palbociclib), Kisqali (ribociclib), and Verzenio (abemaciclib) used to treat some patients with advanced breast cancers may cause rare but severe inflammation of the

lungs. We have approved new warnings about this risk to the prescribing information and Patient Package Insert for the entire class of these cyclin-dependent kinase 4/6 (CDK 4/6) inhibitor medicines. The overall benefit of CDK 4/6 inhibitors is still greater than the risks when used as prescribed.... **Patients** should notify your health care professional right away if you have any new or worsening symptoms involving your lungs, as they may indicate a rare but life-threatening condition that can lead to death. Symptoms to watch for include: Difficulty or discomfort with breathing, Shortness of breath while at rest or with low activity. Do not stop taking your medicine without first talking to your health care professional.... More information is available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-severe-lung-inflammation-ibrance-kisqali-and-verzenio-breast-cancer>

FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease – [8/28/2019]. The Food and Drug Administration (FDA) has received reports that the use of Mavyret, Zepatier, or Vosevi to treat chronic hepatitis C in patients with moderate to severe liver impairment has resulted in rare cases of worsening liver function or liver failure. All these medicines contain a hepatitis C virus (HCV) protease inhibitor and are not indicated for use in patients with moderate to severe liver impairment. In most patients, symptoms resolved or new onset worsening of liver function improved after stopping the medicine. These medicines have been widely used and are safe and effective in patients with no or mild liver impairment.... More information is available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and>

FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR) - [7-26-2019]. The U.S. Food and Drug Administration has approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. We approved these changes, including adding our most prominent Boxed Warning, after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine.

The 10 mg twice daily dose of tofacitinib is not approved for RA or psoriatic arthritis (PsA). This dose is only approved for ulcerative colitis for initial treatment and for long-term use in limited situations. While the increased risks of blood clots and of death were seen in patients taking this dose for RA, these risks may also apply to those taking tofacitinib for ulcerative colitis.... More information is available at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and>

Additional information can be obtained at the FDA’s Drug Safety Communications web page:
<https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications>

When administering prescription and over-the-counter medications to your clients, please be aware of the potential side effects of the medications. Document any changes in the client’s condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the health care provider/prescriber can be informed.

Thank you for your interest in our Medical Alerts and for your continued cooperation with the Office of Ombudsman for Mental Health and Developmental Disabilities. Please call me, at either the toll free or voice numbers above, with any questions or concerns.

Sincerely,

Jo Zillhardt, BSN, RN-BC, PHN
Medical Review Coordinator

Equal Opportunity Employer