PHARMACY NEWSCAPSULE

WISCONSIN DEPARTMENT OF HEALTH SERVICES / DIVISION OF QUALITY ASSURANCE

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APP for That!

PneumoRecs: Surveyors have this Centers for Disease control app on their phones. This app helps determine which pneumococcal vaccine is needed.

The app has been updated to include the October 2024 updated recommendations for pneumococcal vaccines.

Phosphate Binders

People who are on dialysis need to keep their phosphorus levels in a healthy range. Phosphorus is necessary to maintain good health, but high phosphorus levels can lead to heart disease and other complications when a person has chronic kidney disease (CKD) and is on dialysis. Phosphate binders are medications prescribed to dialysis patients to help prevent extra phosphorus from being absorbed from food into the bloodstream.

Phosphate binders prevent the body from absorbing the phosphorus from the food you eat. Phosphate binders help to pass excess phosphorus out of the body in the stool, reducing the amount of phosphorus that gets into the blood. Usually, phosphate binders are taken within 5 to 10 minutes before or immediately after meals and snacks.

As of January 1, 2025, phosphate binders are covered under Medicare. Medicare has transitioned coverage of select oral-only phosphate binders used for patients receiving dialysis away from other Medicare drug coverage and added these medications to the bundle payment established by the End Stage Renal Disease Prospective Payment System (ESRD PPS).

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Phosphate Binder cont.

What is the impact of this change?

Residents of assisted living facilities and nursing homes where they receive all prescription medications, will now receive phosphate binders from the dialysis facility and/or the dialysis pharmacy.

Potential Issues Include:

Payment: A newly admitted resident requiring dialysis and phosphate binders has arrived without their own supply of phosphate binders. The nursing home may need to utilize a contingency supply, or the assisted living facility might have to acquire a small amount from their regular pharmacy until the dialysis facility can provide the necessary supply.
The cost for this supply may fall under the resident's responsibility.

Coordination: Nursing homes and assisted living will need to coordinate with the dialysis facility on phosphate binder supply, delivery and refills. If facilities do not have this relationship already, they will need to establish that as part of their coordinated care.

Packaging: Assisted living or nursing home providers using unit of use packaging (like blister cards) may not receive dialysis medications in the same format from the dialysis facility. This could require repackaging or staff training to administer medications from different packaging. Community Based Residential Facilities (CBRFs) may need to repackage these medications to comply with their requirements of unit of use packaging.

Surveyors in nursing homes, assisted living and end stage renal dialysis facilities may encounter complaints about missing phosphate binders for residents/patients. The survey process should assess communication between providers and physicians, as well as measures taken to address residents' needs until the binders are available. Failure in communication and planning may lead to citations for pharmacy services or medication errors.

Nursing Home Guidance Changes

CMS issued memo QSO 25-07 in November 2024. This memo was revised and reissued as QSO 25-12 on January 15th, 2025. This memo includes an updated Appendix PP and contains many updates including pharmacy updates which are intended to take effect March 24, 2025. The following are the pharmacy changes that nursing home surveyors can review.

General structural changes:

- F758 to F605: All regulatory language was moved from F758 to F605. This includes the unnecessary drug language and all the psychotropic medication regulatory language.
- Guidance: The guidance for F605 and F758 were combined.

Nursing Home Guidance Changes cont.

Key Guidance Changes of Greater Significance:

- Resident Right to be informed or informed consent: Guidance was added for the new F605 and old F757 related to a resident right to refuse initiation or dose increase of medications. The guidance indicates this can be written consent form or it can be documented some other way. Although this guidance is under F605 and F757 this will be a F552 site. The Unnecessary Medication critical element pathway has been updated to include a question about consent and directs surveyors to cite F552 if consent is not present. IMPACT: State law in Wisconsin requires consent for some psychotropic medications in specific situations. This publication https://www.dhs.wisconsin.gov/publications/p0/p00336.pdf helps with this state requirement. This will indicate compliance with F552. Using a form like this for all other medications is not required for compliance at F552. Facilities can choose to document consent in other ways for all the other medications. Currently CMS has not provided guidance on other acceptable practices.

- Gradual Dose Reduction or GDR: The guidance for psychotropic medications requires dose reduction attempts twice in the first year, spaced a month apart, and then annually. The guidance indicates that dose reduction may adhere to practice standards, allowing facilities to implement more restrictive standards. The guidance for clinical contraindications or when dose reductions are unnecessary has been updated. The guidance options for dementia for clinical contraindication was removed. This means that all psychotropics are treated the same. If a facility opts not to do a dose reduction, there must be clinical standards of practice supporting continued use and a specific resident clinical rationale to continue the medication without reduction OR there must have been a previous failed attempt and rationale to continue the medication.

- Adequate indications for use: Definition updated to include psychotropic drugs that do not have in the records that other treatments are clinically contraindicated. When reviewing psychotropic medications, using an alternative to traditional options first may be deemed unnecessary. For example, when psychotropic drugs used off label for something like an antipsychotic medication used specifically for sleep. There are other medications specifically approved for sleep that typically are used first. If the antipsychotic was used first without rationale or documentation, why other traditional treatments have not been used this could be considered unnecessary medication and cited.

Nursing Home Guidance Changes cont.

Important but Low-Impact Guidance Changes for Survey:

- Chemical restraint convenience definition changed: The definition now includes unnecessary medications which intentionally or unintentionally sedate a resident or changes resident behavior specific to sedation.
- Chemical restraint discipline definition changed: The definition now includes an example of using medication to keep a resident in their room as a form of discipline.
- Chemical restraint medical use definition change: The definition now includes cases where a drug originally prescribed for medical use no longer treats symptoms but only sedates the resident.
- Indications for use changed: In summary the guidance requires psychotropics for behaviors the facility needed to show they have out other causes of behavior, the behavior harmful, the behavior persistent and has the facility tried non-pharm interventions. The updated guidance removed the language around persistence and also added that multiple forms of non-pharm interventions should be attempted.
- Multiple psychotropics language added: New guidance requires medical records to document the rationale when switching from one psychotropic to another.
- Gradual Dose Reduction (GDR) Documentation Language: The MDS documentation for GDR has been in place for a while. Appendix PP has new language that documentation must include date of GDR, outcome of GDR and the plan for future GDR attempts. This is partially accomplished by MDS.

Changes will take effect on March 24, 2025, but may be delayed or modified, with further communication to follow if that occurs.

New Drug Approval

The U.S. Food and Drug Administration approved Journavx (suzetrigine) 50 milligram oral tablets, a first-in-class non-opioid analgesic, to treat moderate to severe acute pain in adults. Journavx reduces pain by targeting a pain-signaling pathway involving sodium channels in the peripheral nervous system, before pain signals reach the brain.

Journavx is the first drug to be approved in this new class of pain management medicines.

The most common adverse reactions (greater incidence in JOURNAVX-treated patients compared to placebo-treated patients) were pruritus, muscle spasms, increased creatine phosphokinase, and rash.

The recommended starting Journavx oral dose is 100 mg. Take the starting dose on an empty stomach at least 1 hour before or 2 hours after food. Clear liquids may be consumed during this time (e.g., water, apple juice, vegetable broth, tea, black coffee). Starting 12 hours after the starting dose, take 50 mg of Journavx orally every 12 hours. Take these doses with or without food. Swallow Journavx tablets whole and do not chew or crush.