Implementing Telemedicine Into Your Practice

Help improve access to quality care for your patients who may be out of reach

American Academy of Sleep Medicine (AASM) Recommendations for Telemedicine Best Practices

- Identify a telemedicine platform that suits the needs of your practice[1]
  - Consider cost, hardware/software requirements, security, and user experience
- Consult state regulations regarding telemedicine practice,[1] including:
  - Provider-patient encounters
  - Telepresenter requirements
  - Informed consent
  - Out-of-state practice and licensure
  - Internet prescribing
- Utilize adequate bandwidth and high-resolution video[1,2]
- Ensure that both the provider and the patient are situated in quiet, private, Health Insurance Portability and Accountability Act (HIPAA)–compliant environments[1,2]

Applying AASM Clinical Recommendations to Telemedicine

Mirror clinical care standards for telemedicine services to those of in-office visits, including clinical interview and use of validated scales.[2-4]

AASM-recommended measures of the quality of patient-centered care include the assessment of sleepiness with a validated scale (e.g., the Epworth Sleepiness Scale [ESS]) at every visit and documenting any change from baseline.[3,4]

Important Reminders for Telemedicine or In-Office Visits for Your Patients Taking WAKIX® (pitolisant)

- Assess for efficacy response and tolerability, particularly while titrating WAKIX
- Talk to your patients about how WAKIX works and how to know if they are responding to treatment
- Reiterate that WAKIX should be taken once daily in the morning upon wakening
- Remind patients that ***WAKIX for You***™ is a support program that offers individualized support based on patients' specific needs

Indications and Usage

- WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

Important Safety Information

Contraindications

- WAKIX is contraindicated in patients with severe hepatic impairment.

Please see Important Safety Information continued on next page and accompanying Full Prescribing Information.

For more telemedicine best practices, visit
AASM.org/clinical-resources/telemedicine

Wakix® pitolisant tablets

Important Safety Information (continued)

Warnings and Precautions

- WAKIX® (pitolisant) prolongs the QT interval; avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.
- The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment (see full prescribing information). WAKIX is not recommended in patients with end-stage renal disease (ESRD).

Drug Interactions

- Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. Reduce the dose of WAKIX by half.
- Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%. Dosage adjustments may be required (see full prescribing information).
- H_1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H_1 receptor antagonists.
- WAKIX is a borderline/weak inducer of CYP3A4. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with WAKIX. The effectiveness of hormonal contraceptives may be reduced when used with WAKIX and effectiveness may be reduced for 21 days after discontinuation of therapy.

Adverse Reactions

- In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at ≥2% and more frequently than in patients treated with placebo included headache, upper respiratory infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

Use in Specific Populations

- WAKIX may reduce the effectiveness of hormonal contraceptives. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuing treatment.
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. Patients should be encouraged to enroll in the WAKIX pregnancy registry if they become pregnant. To enroll or obtain information from the registry, patients can call 1-800-833-7460.
- The safety and effectiveness of WAKIX have not been established in patients less than 18 years of age.
- WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is required in patients with moderate hepatic impairment.
- WAKIX is not recommended in patients with end-stage renal disease. Dosage adjustment of WAKIX is recommended in patients with moderate or severe renal impairment.
- Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers; these patients have higher concentrations of WAKIX than normal CYP2D6 metabolizers.

To report suspected adverse reactions, contact Harmony Biosciences, LLC at 1-800-833-7460 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying Full Prescribing Information.

To learn more about WAKIX, visit **WAKIXhcp.com**

References
1. American Academy of Sleep Medicine Telemedicine Implementation Task Force. *Sleep Telemedicine Implementation Guide*. Darien, IL: American Academy of Sleep Medicine; 2017.
2. Singh J et al. *J Clin Sleep Med*. 2015;11(10):1187-1198. **3.** Morgenthaler TI et al. *J Clin Sleep Med*. 2015;11(3):279-291. **4.** Krahn LE et al. *J Clin Sleep Med*. 2015;11(3):335-355.

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