HHSC Psychiatric Executive Formulary Committee Minutes

The HHSC Psychiatric Executive Formulary Committee (PEFC) convened on April 28, 2023 via MS Teams. The meeting was called to order by Dr. Chadalavada, representing Dr. Moron as Chair, at 9:31 a.m.

Members

Member Names	Attendance	Member Names	Attendance
Yekini Adeyemi, RN	Present	David Moron, MD- Chair	Absent
Angela Babin, RPh	Present	Leah Nunez, PharmD	Present
John Bennett, MD	Present	Brittany Parmentier, PharmD	Absent
Giovanna Betancourt, PharmD	Absent	Kasey L. Pena, PharmD- Secretary	Present
Rakesh Chadalavada, MD	Present	Kenda Pittman, PharmD	Present
German Corso, MD	Present	Sangeetha Rajan, MD	Present
Brad Fitzwater, MD	Present	Rishi Sawhney, MD	Present
Jon Guidry, MD	Absent	Lesia Trickett, MD	Absent
Catherine Hall, PharmD	Present	Ashton Wickramasinghe, MD	Present
Dana Hopkins, RN	Present	Patrick Young, MD	Absent
Jeffery Matthews, MD	Absent		

Guests Present: Tonya Barrios, State Hospitals Central Administration; Kristen Neumeister, PharmD, North Texas State Hospitals; Candace Jones, MD, PGY-4 Adult Psychiatry Resident, Dell Medical School; Dr. Chloe Yuan, MD, PGY-5 Child Psychiatry Fellow, Dell Medical School

Opening

Introduction and Other Information

None.

Conflict of Interest Disclosures

The committee members present did not disclose any new conflicts of interest.

Review of Minutes

The minutes from the January 27, 2023 meeting were approved as previously distributed.

Unfinished Business

None.

New Business

Applicability of the TAC medication consent rule to outpatient settings

The committee discussed the medication consent rule and how it relates to outpatient settings. TAC 414.I. requires consent for administration of psychoactive medication in mental health services in regard to medication administration. Dr. Sawhney stated the LMHAs have been getting consent forms signed for prescriptions, but since they are not administering these medications, there was discussion regarding whether these consent forms are necessary. Discussion at the LMHA level will be ongoing.

New Drug Applications

Covid vaccines

A new drug application has been submitted to add all mRNA Covid-19 vaccines to the formulary. After discussion, the committee agreed to wait until the vaccines are FDA approved. The committee will reconsider adding these vaccines to the formulary in the future.

Dexmedetomidine (Igalmi®)

Presented by Dr. Pena. Please refer to Appendix A for the monograph that was considered when determining action by the committee.

After discussion of the monograph, the committee approved the addition of Dexmedetomidine (Igalmi®) to the formulary as a Reserve Drug in the Psychotropic Agents-Miscellaneous Anxiolytics and Hypnotics section. The committee will follow up in six months to see how often this medication is being ordered.

The formulary check list was completed and no issues were detected.

Psychotropic Medication Audit Criteria & Guidelines Review

The committee reviewed and approved recommended revisions to the following audit criteria documents:

- Audit criteria template review
- clozapine (requested revision to monitoring section)
- lithium (requested revision to monitoring section)
- clonidine, guanfacine
- atomoxetine
- beta blockers

The stimulants audit criteria will be pended until the next meeting.

The updated documents will be posted to the PEFC website.

Psychotropic Monitoring Guidelines Review

The committee reviewed and approved updates to the Psychotropic Monitoring Guidelines that were based on revisions to the audit criteria approved at this meeting.

The updated document will be posted to the PEFC website.

Adverse Drug Reaction Reports

The committee discussed one adverse drug reaction report that was received from the field. This adverse event was reported to the FDA's MedWatch program.

ADR: Acute kidney injury, hyperkalemia/Bactrim

An 85-year-old Hispanic male was transferred from a maximum-security state facility to the local psychiatric hospital on January 17, 2023. He has a history of major neurocognitive disorder (multiple causes), AUD in controlled environment (MRI showed mid-line cerebellar lesion from ethanol), diabetes mellitus type 2, hypertension, hyperlipidemia, chronic kidney disease, congestive heart failure, abdominal hernia, blind in the right eye, posterior reversible encephalopathy syndrome, status post myocardial infarction, history of aspiration pneumonia, stenosis of right internal carotid artery, low B12, peripheral neuropathy. Upon admission to the local facility, patient complained of painful right big toe that was interfering with sleep. The toe was scabbed over and red and was being treated with mupirocin at the maximum-security facility (MSF). It was later found that he had received a course of doxycycline at the MSF.

On 1/18/23, BUN = 33, Cr = 1.63, k = 5.0, GFR = 38 ml/min, CrCl = 28 ml/min (adjusted body weight).

Bactrim DS, 1 tablet twice daily started 1/18/23, Augmentin 500-125 started 1/20/23 and chem 7 ordered for 1/23/23.

On 1/19/23, patient told the internist that he has had the wound for about 2 months. An x-ray was ordered to rule out osteomyelitis. He also told the internist that he had used an inhaler in the past and pulmonary function tests were ordered.

Over the weekend, patient fell in the bathroom and hit his face on his walker. He was unresponsive and the RN had to perform a sternal rub. He vomited shortly afterward. The patient was also short of breath and received Duoneb.

On 1/23/23, BUN = 45, Cr = 2.1, k = 5.5 (3.5-5.2), gfr = 28. The internist stopped Bactrim and furosemide and wrote an order to push fluids. Repeat lab drawn later that day showed BUN = 49, Cr = 2.6, k = 6.1. He was transferred to the community hospital on albuterol, amlodipine 7.5 mg daily in the morning, Augmentin 500-125, 1 tablet twice daily (1/20-1/27/23), aspirin 81 mg, atorvastatin 40 mg, carvedilol 25 mg twice daily, gabapentin 100 mg at bedtime, insulin glargine 30 units SQ daily in

the morning (started 1/20/23), insulin regular (started 1/20/23) 10 units in the morning, 7 units at noon, 7 units at dinner, Metamucil, mupirocin ointment (right big toe), pantoprazole 40 mg, budesonide/formoterol started 1/20/23, tamsulosin 0.4 mg daily at bedtime, vit b12.

Patient was at the community hospital from 1/23-2/2/23, treated for acute kidney injury (AKI), hyperkalemia. Angiogram showed critical stenosis in foil, balloon angioplasty performed. Echo showed diastolic dysfunction. Clopidogrel added and gabapentin increased to 200 mg.

AKI, hyperkalemia from Bactrim DS, 1 tablet twice daily, used to treat diabetic foot infection. On 1/18/23 when Bactrim DS started, CrCl = 28 ml/min. Per IDSA, usual dose for treatment of diabetic foot is Bactrim DS 2 tablets twice daily. Per Sanford, the dose is Augmentin plus Bactrim DS, 1-2 tablets twice daily. Patient's creatinine clearance was in the 15 to 30 ml/min range and Bactrim DS 2 tablets twice daily dose was reduced 50% to 1 tablet twice daily, per Lexicomp and the PI.

Resources

The committee reviewed and approved recommended revisions to the following resource documents:

- Foods Containing Tyramine: Removed this resource and added a link to a recommended resource in the "Resource link" document.
- Resource links
- Fluphenazine to haloperidol conversion table

The updated documents will be posted to the PEFC website.

Drug Formulary Sectional Review

In reviewing the formulary drug listings for Endocrine, Osteoporosis, and Genitourinary, the following changes were approved:

- Endocrine Agents – Estrogens
  - estradiol – remove brand name Estraderm
- Endocrine Agents – Androgens
  - testosterone – remove brand name Androlan
- Osteoporosis Agents
  - Calcitonin salmon (Miacalcin) nasal spray – remove
  - Ibandronate – remove brand name Boniva
- Genitourinary Agents – Urinary Alkalinizers
  - Potassium Citrate Combinations – remove brand names Polycitra-LC, Polycitra K
  - Sodium Citrate-Citric Acid – remove brand name Bicitra
- Genitourinary Agents – Urinary Anticholinergics
  - Darifenacin – remove brand name Enablex
- Genitourinary Agents – Urinary Cholinergics

    - Bethanechol – remove brand name Urecholine
- Updated Cost Index of several items

The updated formulary will be posted on the PEFC website.

Other Formulary Changes

The committee also approved the following change to the formulary:

- diclofenac gel (Voltaren Gel)– remove from Reserve Use

The updated formulary will be posted on the PEFC website.

Quarterly Non-Formulary Drug Justification Report

For the second quarter of fiscal year 2023 (December 2022 to February 2023), only the state hospitals reported use of non-formulary agents. The state supported living centers (SSLCs) currently do not have the capability to obtain non-formulary drug usage reports from their computer system but are working with the vendor to make this reporting possible. The following were the top five non-formulary agents, by number of orders, that were prescribed in the state hospitals during the second quarter of fiscal year 2023:

- Molnupiravir
- Quercetin
- Zinc gluconate
- Paxlovid
- Midol Menstrual Complete

Issues from the Chief Medical Officer, State Hospitals

Dr. Matthews was not present to present a report.

Issues from the Medical Services Coordinator, SSLCs

Dr. Wickramasinghe shared with the committee the SSLCs are continuing to work on the Antibiotic Stewardship Program.

Dr. Wickramasinghe also announced he will be conducting the second scheduled luncheon on aspiration pneumonia.

Drug Shortages, Recalls, and FDA Safety Communications

The FDA has issued the following safety communications and recalls that may impact our facilities:

Shortages

The following medications are in shortage but are still available to be ordered (4/20/2023):

- Albuterol sulfate inhalation solution (NEW)

- Amphetamine salt combos
- Amoxicillin oral powder for suspension
- Clonazepam (NEW)
- Lidocaine injection (NEW)
- Lorazepam injection
- Sterile water for injection

Recalls

- Atovaquone oral suspension (Camber brand): recalled due to potential Baillus cereus contamination
- Dabigatran capsules (Ascend Laboratories): recalled due to detection of impurity
- Brimonidine tartrate ophthalmic solution (Apotex): recalled due to potential lack of sterility

Safety-related Labeling Changes

- Lorazepam injection: FDA added pregnancy and nursing related precautions, advising that exposure can result in sedation and withdrawal for the newborn/infant.
- Carbamazepine: FDA added precautions related to cardiac conduction disturbance, AV block, hepatic effects (including a recommendation to discontinue based on clinical judgement if evidence of hepatic dysfunction seen in labs). Also added additional information related to drug interactions, including examples. Also added that there have been reports of developmental disorders and congenital anomalies in newborns that were exposed to carbamazepine in utero.
- Depakote: FDA added information related to interaction with methotrexate causing decreased serum valproate levels.

News Briefs

The following information was shared with the committee members:

FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines

FDA News Release (4/18/2023). The Moderna and Pfizer COVID-19 bivalent mRNA vaccine EUAs were modified to authorize the bivalent vaccines to be used for all doses administered to individuals 6 months of age and older. The monovalent Moderna and Pfizer vaccines are no longer authorized for use in the US.

FDA Approves First Over-the-Counter Naloxone Nasal Spray

FDA News Release (3/29/2023). The FDA approved a 4mg Narcan (naloxone) nasal spray for OTC nonprescription use. The timeline of availability of this product is not currently known.

Open Forum

The committee discussed the process of reviewing newly FDA approved formulations of medications already on the HHSC formulary and whether a full monograph review is necessary in these instances. Dr. Babin shared with the committee their facility has an abbreviated form for new formulations and brand names of a formulary medication. The clinical pharmacist members of the committee will convene to develop an abbreviated monograph template, and the committee will review at a future meeting. At this time, the committee will continue to follow the current process of reviewing a full monograph for all new drug applications.

Next Meeting Date

The next meeting is scheduled for July 28, 2023.

Adjourn

There being no further business, the meeting was adjourned at 1:47 p.m.

Approved: *David Moron*

David Moron, MD, Chairman

Minutes Prepared by:
Tonya Barrios, PhTR
Reviewed by:
Kasey L. Pena, PharmD

Appendix A

Dexmedetomidine (Igalmi®)

Classification

Alpha-2-adrenergic agonist; Sedative

Pharmacology

Selective alpha-2-adrenoceptor agonist with anesthetic and sedative properties. The sedative properties are thought to be due to activation of G-proteins by alpha-2a-adrenoceptors in the brainstem resulting in inhibition of norepinephrine release.

Indication

Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.

Pharmacokinetics

Igalmi® is a film that should be administered sublingually or buccally. The mean time for the film to dissolve in the mouth was 6-8 minutes for sublingual administration and 18 minutes for buccal administration.

Pharmacokinetic Parameter	Details

Absorption	• Absolute bioavailability is 72% (sublingual) or 82% (buccal).
	• Mean maximal plasma concentrations were reached two hours after both routes of administration. Mean Cmax of 143 ng/L (sublingual) and 144 ng/L (buccal). Mean AUC 851 hour*ng/L (sublingual) and 584 hour*ng/L (buccal).
	• Effects of water:
	  ○ When water was consumed two hours post dose, the total exposure was comparable for both administration routes.
	  ○ Sublingual: Consumption of water 15 minutes as compared to two hours post dose had minimal effect on absorption.
	  ○ Buccal: Effects of water intake before two hours post dose not evaluated.

Distribution	• Steady state volume of distribution was approx. 118 L. • Avg protein binding was 94% in healthy subjects, similar in males and females. Fraction of protein bound was significantly lower in subjects with hepatic impairment. • Protein binding displacement was not noted for either dexmedetomidine or concomitant medications studied.
Metabolism	• Undergoes direct glucuronidation. • Undergoes cytochrome P450 metabolism via CYP2A6 (major) and CYP1A2, CYP2E1, CYP2D6, CYP2C19 (minor).
Excretion	• Elimination half-life 2.8 hours after sublingual or buccal administration. • For intravenous administration, 95% eliminated in urine and 4% in feces. No unchanged dexmedetomidine found in urine.

Dosage/Administration

Dosage: See dosing tables below.

Initial dosage depends on agitation severity.

If agitation persists, up to two additional doses at lower strengths depending on the agitation severity can be administered at least two hours apart. Prior to administration of subsequent doses, assess vital signs including orthostatic measurements. Additional doses are not recommended with blood pressures less than 90/60, heart rate less than 60, or postural decrease of 20/10 or more.

Dosage Recommendations for Igalmi® in Adults (table adapted from Igalmi® package insert)

Agitation Severity	Initial Dose	Optional Additional Doses (up to two)	Maximum Recommended Total Daily Dose
Mild or Moderate	120 mcg	60 mcg	240 mcg
Severe	180 mcg	90 mcg	360 mcg

Dose adjustment in geriatric population and hepatic impairment are recommended.

Dosage Recommendations for Igalmi® in Adults with Hepatic Impairment and Geriatric Patients (table adapted from Igalmi® package insert)

Patient Population	Agitation Severity	Initial Dose	Optional Additional Doses (up to two)	Maximum Recommended Total Daily Dose
Mild or Moderate Hepatic Impairment (Child-Pugh Class A to Class B)	Mild or moderate	90 mcg	60 mcg	210 mcg
Mild or Moderate Hepatic Impairment (Child-Pugh Class A to Class B)	Severe	120 mcg	60 mcg	240 mcg
Severe Hepatic Impairment (Child-Pugh Class C)	Mild or moderate	60 mcg	60 mcg	180 mcg

Patient Population	Agitation Severity	Initial Dose	Optional Additional Doses (up to two)	Maximum Recommended Total Daily Dose
Severe Hepatic Impairment (Child-Pugh Class C)	Severe	90 mcg	60 mcg	210 mcg
Geriatric Patient (≥65 years old)	Mild, moderate, or severe	120 mcg	60 mcg	240 mcg

Preparation and Administration:

- A healthcare provider should prepare the dose by opening the pouch and then give the appropriate dose to the patient with instructions on how to self-administer. This medication should be administered under the supervision of a healthcare provider with monitoring of vital signs and alertness to prevent falls and syncope.
- Dosage preparation by healthcare provider:
  - Open the pouch with clean, dry hands.
  - This medication is available in 120 mcg and 180 mcg dosage strengths. These can be cut in half to obtain the 60 mcg and 90 mcg doses. If a half of a film is needed, remove the film with clean, dry hands and cut in half with clean, dry scissors. Place the half film for administration back into the pouch and discard the unused half.
  - Give the pouch to the patient with clean, dry hands. Instruct the patient to remove the film and place under the tongue or behind lower lip.
- This medication should be administered sublingually or buccally, it should not be chewed or swallowed.
- Eating and drinking should be avoided for 15 minutes after sublingual administration, one hour after buccal administration.
- This medication should be kept in the foil pouch, it should be immediately administered once the pouch is opened and the dose is prepared.

Use in Special Populations

- Pediatrics/Adolescents: Safety and efficacy have not been established.
- Geriatric: No observed difference in pharmacokinetics based on age, but adjusted dosing recommendations are provided for patients 65 years of age or older. See Dosing/Administration above.
- Renal: No significant difference in pharmacokinetics based on renal function difference.

- Hepatic: In patients with Child-Pugh Class A, B, C hepatic impairment, clearance was reduced and dosing adjustment is recommended. See Dosing/Administration above.
- Pregnancy and Breastfeeding: Safety and efficacy have not been established.

Contraindication

None

Precautions

The safety and effectiveness of Igalmi® have not been established beyond 24 hours from the first dose.

Hypotension, Orthostatic Hypotension, Bradycardia

- Dose dependent hypotension, orthostatic hypotension, and bradycardia can be seen. These may be more pronounced in patients with hypovolemia, diabetes, chronic hypertension or in geriatric patients.
- In clinical studies, patients were excluded if they received alpha-1 noradrenergic blockers, benzodiazepines, other hypnotics or antipsychotic drugs four hours prior to study drug; also excluded if they had a history of syncope, low blood pressure, HR <55, evidence of hypovolemia or orthostatic hypotension.

Blood Pressure and Heart Rate Changes (table adapted from Igalmi® package insert)

Effect	Igalmi® 180 mcg	Igalmi® 120 mcg	Placebo
Mean SBP Decrease (mmHg)	15	13	1
Mean DBP Decrease (mmHg)	8	7	<1
Mean Heart Rate Decrease (BPM)	9	7	3
Percent experiencing SBP ≤ 90 mmHg and SBP decrease ≥ 20 mmHg within 24 hrs	13%	8%	<1%
Percent experiencing DBP ≤ 60 mmHg and DBP decrease ≥ 10 mmHg within 24 hrs	19%	17%	2%
Percent with HR ≤ 50 BPM and HR decrease ≥ 20 BPM within 24 hrs	4%	3%	0%

  - Monitoring of vital signs and orthostatic vital signs occurred at regular intervals beginning at 30 min and up to 8 hours post dose. The maximum effect on BP and HR (including positional) were observed at two hours post dose.

- 16-18% experienced orthostatic hypotension (SBP decrease ≥20 mmHg or DBP decrease ≥10 mmHg) 2 hours post dose, with higher incidence at higher doses, compared to 9% on placebo.
- 6-7% experienced HR ≤50 within 2 hours of dosing, with higher incidence at higher doses, compared to 1% on placebo.

- Note that for intravenous dexmedetomidine, there have been serious reports of hypotension and bradycardia (some resulting in fatalities). These reports have been seen in young, healthy adult volunteers after receiving rapid intravenous or bolus administration of dexmedetomidine.

QT Interval Prolongation

Dexmedetomidine can cause concentration dependent QT prolongation. Avoid in patients at risk of torsades de pointes (known QT prolongation, history of arrhythmia, symptomatic bradycardia, hypokalemia, hypomagnesemia, receiving other drugs known to prolong QT interval).

QTcF Increase from Baseline (table adapted from Igalmi® package insert)

Dose	Mean QTcF Increase from Baseline
120 mcg single dose	6
120 mcg + 2 additional doses of 60 mcg	8
180 mcg	8
180mcg + 2 additional doses of 90 mcg	11

Somnolence

- In clinical studies, somnolence was reported in 22-23% of patients treated with Igalmi® compared to 6% of those treated with placebo.
- Patients should avoid performing activities requiring mental alertness for at least 8 hours following administration.

Risk of Withdrawal Reactions

- Symptoms of withdrawal have been seen within 24 hours of discontinuing intravenous dexmedetomidine after receiving intravenous dexmedetomidine for up to 7 days. Withdrawal reactions may include nausea, vomiting, agitation.
- Igalmi® was not studied for longer than 24 hours post dose.

Tolerance and Tachyphylaxis

- Use of intravenous dexmedetomidine for longer than 24 hours has been associated with tolerance and tachyphylaxis.
- Igalmi® was not studied for longer than 24 hours post dose.

Adverse Effects

Two placebo controlled randomized clinical studies evaluating the safety of Igalmi® included 507 hemodynamically stable adult patients with agitation related to schizophrenia or bipolar disorder who received at least one dose of Igalmi® (180mcg or 120 mcg) or placebo. Second doses were administered as recommended in the dosing recommendations above as needed.

Adverse Reactions Reported in at least 2% of Patients treated with Igalmi® (table adapted from Igalmi® package insert)

Adverse Reaction	Igalmi® 180 mcg, 120 mcg	Placebo
Somnolence	23, 22	6
Oral paresthesia or hypoesthesia	7, 6	1
Dizziness	6, 4	1
Hypotension	5, 5	0
Orthostatic hypotension	5, 3	<1
Dry Mouth	4, 7	1
Nausea	3, 2	2
Bradycardia	2, 2	0
Abdominal discomfort	2, 0	1

Monitoring

Healthcare provider should monitor vital signs and alertness after administration to prevent falls and syncope. Peak effects on vital signs seen at two hours post dose.

Interactions

- Avoid concomitant use with drugs that prolong the QT interval due to potential additive effects increasing the risk of arrhythmia
- Concomitant use with medications that cause CNS depression (ie anesthetics, sedatives, hypnotics, opioids) due to potential additive effects. If using

Igalmi® with an anesthetic, sedative, hypnotic, or opioid, consider reduction in dosage of Igalmi®.

Efficacy

The effectiveness of Igalmi® in the treatment of acute agitation associated with schizophrenia or bipolar I/II disorder in adults was established in two randomized, double-blind, placebo-controlled fixed studies. Study 1 included 380 patients diagnosed with schizophrenia, schizoaffective, or schizophreniform disorder aged 18 to 71 years of age (mean 46). 37% female, 63% male; 78% black, 20% white, 1% multiracial, 1% Asian. Study 2 included 378 patients diagnosed with bipolar I or bipolar II disorder aged 18 to 70 years (mean 47). 55% female, 45% male; 56% black, 41% white, 1% Asian, 1% multiracial, 1% other. Patients were admitted to a clinical research unit or hospital and observed for at least 24 hours after dosage administration.

The Positive and Negative Syndrome Scale-Excited Component (PEC) was used. This is an investigator-rated instrument containing 5 items (poor impulse control, tension, hostility, uncooperativeness, excitement) scaled from 1 to 7 (1=absent, 7=extremely severe) with higher total score indicating greater overall severity of symptoms. The patients enrolled had to have a PEC score of 14 or greater and at least one individual item score of at least 4. Mean baseline PEC scores were similar in all treatment groups. Patients were randomized to receive a single sublingual dose of Igalmi® 180 mcg, 120mcg, or placebo with the primary endpoint being the change from baseline in PEC score (two hours after initial dose). The secondary endpoint was the time to effect onset (PEC measured at 10, 20, 30, 45, 60, 90 min after initial dose).

The mean change from baseline in the PEC total score at two hours after the first dose in patients treated with both doses of Igalmi® was statistically greater than patients who received placebo. In Study 1 (Schizophrenia), the decrease in PEC from baseline was statistically significant when compared to placebo at 20 minutes after the 180 mcg dose and at 30 minute after the 120 mcg dose. In Study 2 (Bipolar), the decrease in PEC from baseline was statistically significant when compared to placebo at 20 minutes for both doses.

Dosage Forms/Cost (AWP)

Igalmi® is available in 120 mcg and 180 mcg films.

Igalmi® is sold in packages of 10 at AWP $1,260 ($126 per film). It is available through MMCAP wholesalers, as a drop-ship item in some cases.

Summary/Conclusion

Currently on formulary, oral agents for acute agitation for schizophrenia or bipolar disorder include aripiprazole, olanzapine, ziprasidone, haloperidol (not FDA indicated), and lorazepam (not FDA indicated). There are cases where a patient is not a candidate for or does not respond to one of these agents. Igalmi® has a different mechanism of action compared to the above agents, is not a controlled

substance, and the statistically significant decrease in an objective measure of agitation at 20 minutes post dose is faster than many of our current options. Igalmi® is an alpha-2 adrenergic receptor agonist, in the same class as formulary agents clonidine and guanfacine. Dexmedetomidine has a much higher potency and agonist efficacy at alpha-2 receptors at much lower doses. It is important to consider that Igalmi® is self-administered so the patient willingness and ability to understand administration instructions should be considered. It would be beneficial to have an alternative option to treat acute agitation.

Recommendation

Igalmi® should be added to the formulary.

References

1. Igalmi®. Prescribing information. BioXcel Therapuetics, Inc; July 2022. Accessed April 14, 2023.
2. Igalmi® Dosage and Administration Guide. BioXcel Therapeutics, Inc; July 2022. Accessed April 14, 2023.
3. Preskorn SH, Zeller S, Citrome L, Finman J, Goldberg JF, Fava M, Kakar R, De Vivo M, Yocca FD, Risinger R. Effect of Sublingual Dexmedetomidine vs Placebo on Acute Agitation Associated With Bipolar Disorder: A Randomized Clinical Trial. JAMA. 2022 Feb 22;327(8):727-736. doi: 10.1001/jama.2022.0799. PMID: 35191924; PMCID: PMC8864508.
4. Citrome L, Preskorn SH, Lauriello J, Krystal JH, Kakar R, Finman J, De Vivo M, Yocca FD, Risinger R, Rajachandran L. Sublingual Dexmedetomidine for the Treatment of Acute Agitation in Adults With Schizophrenia or Schizoaffective Disorder: A Randomized Placebo-Controlled Trial. J Clin Psychiatry. 2022 Oct 3;83(6):22m14447. doi: 10.4088/JCP.22m14447. PMID: 36198061.

Date: April 28, 2023
Prepared by: Kasey Leggette Peña, PharmD, BCPP