PHARMACY COVERAGE GUIDELINE

LUMRYZ (sodium oxybate) extended-release suspension
Sodium oxybate solution
XYREM® (sodium oxybate, GHB) solution
XYWAV™ (calcium, magnesium, potassium, sodium oxybates) solution
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Lumryz (sodium oxybate) extended-release oral suspension, sodium oxybate oral solution, Xyrem (sodium oxybate) oral solution, Xywav (calcium, magnesium, potassium, sodium oxybate) oral solution, and/or generic equivalent (if available) are considered ***medically necessary*** when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Neurologist or Pulmonologist board certified as a sleep medicine specialist

2. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Cataplexy in Narcolepsy in an individual who is **ONE** of the following ages:
        i. **For sodium oxybate, Xyrem, or Xywav**: Individual is 7 years of age or older
        ii. **For Lumryzr**: Individual is 18 years of age or older

    b. Idiopathic Hypersomnia: **For Xywav only**: Individual is 18 years of age or older

3. Individual does **NOT** have another medical condition known to cause or contribute to sleepiness

4. Individual's diagnosis is confirmed by the following:
    a. For Narcolepsy:
        i. Individual has daily periods of irrepressible (uncontrollable) need to sleep or daytime lapses into sleep occurring for at least three months
        ii. **ONE** or **BOTH** of the following:
            1. Clear history of cataplexy and **EITHER**:
                a. A mean sleep latency of ≤ 8 minutes and ***two or more*** sleep onset REM sleep periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques **OR**
                b. A SOREMP (within 15 minutes of sleep onset) on nocturnal polysomnogram (PSG) may replace one of the SOREMPs on the MSLT
            2. CS hypocretin-1 concentration, is low measured by immunoreactivity is either ≤ 110 pg/mL or < 1/3 of mean values obtained in normal subjects with the same standardized assay
        iii. Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

    b. For Idiopathic Hypersomnia:
        i. Individual who complains of chronic excessive daytime sleepiness (EDS) with long unrefreshing daytime naps and difficulty arousing from sleep
        ii. Individual has daily periods of irrepressible (uncontrollable) need to sleep or daytime lapses into sleep occurring for at least three months
        iii. Multiple sleep latency test (MSLT) documents ***less than two*** sleep onset REM sleep periods (SOREMPs) or no SOREMPs if the REM sleep latency on the preceding polysomnogram was less than or equal to 15 minutes
        iv. **ONE** of the following:
            1. Mean sleep latency of ≤ 8 minutes
            2. Total 24-hour sleep time is greater than or equal to 660 minutes (typically 12-14 hours) on a 24-hour polysomnography or by wrist actigraphy in association with a sleep log
        v. There is ***no*** history of cataplexy
        vi. If measured, CS hypocretin-1 concentration ***is not*** low or deficient

vii. Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)

5. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for:
   a. Cataplexy in narcolepsy a three-month trial of:
      i. **TWO** drugs for narcolepsy:
         1. Methylphenidate (or an amphetamine)
         2. Modafinil
      ii. **TWO** drugs from REM sleep-suppressing drugs for cataplexy like:
         1. Strattera (atomoxetine)
         2. Duloxetine
         3. Clomipramine
         4. Prozac (fluoxetine)
         5. Vivactil (protriptyline)
         6. Effexor XR (venlafaxine)
   b. Idiopathic hypersomnia a three-month trial of each of the following:
      i. Methylphenidate (or an amphetamine)
      ii. Modafinil

6. **If available, for EITHER Lumryz (sodium oxybate), Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium, sodium oxybate)**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic sodium oxybate** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. **If available, additional criteria for Lumryz (sodium oxybate) extended-release oral suspension**: Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. There are **NO** FDA-label contraindications such as:
   a. Simultaneous use with alcohol
   b. Simultaneous use with **sedative-hypnotic medications** (such as benzodiazepine sedative-hypnotics or non-benzodiazepine sedatives-hypnotics)
   c. Individual with succinic semi-aldehyde dehydrogenase deficiency. A rare inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia

9. Individual is **NOT** receiving other drugs known to cause or contribute to sleepiness (benzodiazepines such as clonazepam, lorazepam, diazepam etc., sedating antidepressants or antipsychotics, sedating antiepileptic agents, general anesthetics, muscle relaxants, barbiturates, opioids, and others) **OR** there is a coordinated care treatment plan to taper their use

10. Individual does **NOT** use alcohol

11. Individual is **not** using in combination with armodafinil (generic or brand Nuvigil), Sunosi (solriamfetol), Wakix (pitolisant), or another oxybate product

12. Individual has been evaluated and must not have an active addiction to illicit substances or prescription drugs or a history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacy or multiple controlled substances)

13. There must be coordination of care performed between different prescribers for **ALL** controlled substances

14. There is documentation for a **random urine or blood tests** twice a year that is negative for drugs of abuse and alcohol (most recent report must be submitted with request)

15. There is documentation of **PDMP (Prescription Drug Monitoring Program) reviewed** by the prescriber every time a prescription for controlled substance is provided.

16. There are no significant interacting drugs

Initial approval duration:
Sodium Oxybate: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Xyrem: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Xywav: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Lumryz: 6-9 gms packet/night x 30 days (up to 30 packets) monthly for 6 months

- **Criteria for continuation of coverage (renewal request):** Lumryz (sodium oxybate) extended-release oral suspension, sodium oxybate oral solution, Xyrem (sodium oxybate) oral solution, Xywav (calcium, magnesium, potassium, sodium oxybate) oral solution, and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Neurologist or Pulmonologist board certified as a sleep medicine specialist

2. Individual's condition has responded while on therapy with response defined as the following:
    a. Narcolepsy with cataplexy response is defined by improvement in **TWO** of the following:
        i. Achieved and maintains at least a 25% reduction in the frequency of cataplexy attacks over baseline
        ii. Achieved and maintains at least a 25% reduction in the severity of cataplexy attacks over baseline
        iii. Improvement in Epworth Sleepiness Scale of at least 3 points
    b. Idiopathic hypersomnia response is defined by improvement in **TWO** of the following:
        i. Improvement in Epworth Sleepiness Scale of at least 3 points

ii. Decrease in morning sleep inertia
iii. Decrease in naps or decrease in total duration of sleep in 24 hours

3. Individual has been adherent with the medication

4. **For Xyrem (sodium oxybate)**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic sodium oxybate** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. **If available, for Xywav (calcium, magnesium, potassium, sodium oxybate)**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. **If available, for Lumryz (sodium oxybate) extended-release oral suspension**: Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual does **NOT** have another medical condition known to cause or contribute to sleepiness

8. Individual is **NOT** receiving other drugs known to cause or contribute to sleepiness (benzodiazepines such as clonazepam, lorazepam, diazepam etc., sedating antidepressants or antipsychotics, sedating antiepileptic agents, general anesthetics, muscle relaxants, barbiturates, opioids, and others) **OR** there is a coordinated care treatment plan to taper their use

9. There must be coordination of care performed between different prescribers for **ALL** controlled substances

10. Individual does **NOT** use alcohol

11. Individual is **not** using in combination with armodafinil (generic or brand Nuvigil), Sunosi (solriamfetol), Wakix (pitolisant), or another oxybate product

12. Individual has been evaluated and must not have an active addiction to illicit substances or prescription drugs or a history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacy or multiple controlled substances)

13. There is documentation for a **random urine or blood tests** twice a year that is negative for drugs of abuse and alcohol (most recent report must be submitted with request)

14. There is documentation of **PDMP (Prescription Drug Monitoring Program) reviewed** by the prescriber every time a prescription for controlled substance is provided

15. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Seizure
        ii. Respiratory depression
        iii. Decreases in level of consciousness
        iv. Coma
        v. Psychosis/hallucinations/paranoia
        vi. Agitation
        vii. Depression/suicidality
        viii. Sleepwalking

16. There are no significant interacting drugs

Renewal duration:
Sodium Oxybate: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Xyrem: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Xywav: 6-9 gms (18mL)/night x 30 days (up to 540mL) monthly for 6 months
Lumryz: 6-9 gms packet/night x 30 days (up to 30 packets) monthly for 6 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Sodium oxybate solution, **Xyrem** (sodium oxybate) solution and **Xywav** (calcium, magnesium, potassium, sodium oxybates) solution are central nervous system depressants indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age or older with narcolepsy. Xywav (calcium, magnesium, potassium, sodium oxybates) solution is also indicated for the treatment of idiopathic hypersomnia in an individual 18 years of age or older.

Lumryz (sodium oxybate) extended-release oral suspension is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

For ease of discussion, these products will be referred to as “oxybates.”

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The American Academy of Sleep Medicine has subdivided narcolepsy into two types: narcolepsy type 1 and narcolepsy type 2. In both EDS is an essential feature, with cataplexy a core feature in narcolepsy type1. Both types require laboratory tests to confirm the diagnosis. Laboratory testing includes sleep laboratory testing with overnight polysomnography (PSG) followed by a multiple sleep latency test (MSLT) and may also include cerebrospinal fluid (CSF) assessment of hypocretin-1 levels.

PSG testing, together with a MSLT, is indicated for assessing the potential for the presence of narcolepsy. PSG testing also helps identify whether other sleep pathologies, such as obstructive sleep apnea, are present. It can identify the nighttime occurrence of sleep onset rapid eye movement periods (SOREMP). A SOREMP on a nocturnal PSG is a highly specific marker for narcolepsy in the absence of another sleep disorder, but it has low sensitivity. The MSLT is indicated as part of the evaluation of patients with the potential for narcolepsy to confirm the diagnosis and is performed immediately following overnight polysomnography. The MSLT assesses the ability or tendency to fall asleep (as indicated by mean sleep latency, or time to sleep onset) during normal waking hours and the presence of SOREMP.

A normal sleep cycle is 100-110 minutes long and starts with non-rapid eye movement (NREM) sleep before transitioning to rapid eye movement (REM) sleep after 80-100 minutes. People with narcolepsy quickly enter REM sleep within a few minutes of falling asleep.

Narcolepsy is a chronic neurologic disorder of the central nervous system characterized by the brain's inability to control sleep-wake cycles, resulting in EDS and intermittent bouts of REM sleep during wakefulness. At various times throughout the day, individuals with narcolepsy experience irresistible and sudden bouts of sleep, which can last from a few seconds to several minutes. In addition to EDS, other major symptoms of narcolepsy include cataplexy (a sudden loss of voluntary muscle tone), hypnagogic hallucinations (vivid dream-like often frightening tactile images or hallucinations during sleep onset or upon waking), and sleep paralysis (brief episodes of total paralysis, also during sleep onset or upon waking). Most individuals experience poor sleep quality that can involve frequent awakenings during nighttime sleep, and other sleep disorders. Sleep may be disrupted by insomnia, vivid dreaming, sleep talking, acting out while dreaming, and periodic leg movements.

Cataplexy occurs in approximately 70% of individuals with narcolepsy. It is believed to be due to loss of the hypothalamic neuropeptide orexin/hypocretin, as demonstrated by low to undetectable levels of hypocretin in the cerebral spinal fluid. Oxrexins/hypocretins are wake active and increase the firing rate of neurons in areas of the brain responsible for arousal and wakefulness. Loss of orexin neurons can result in hyper-somnolence and loss of muscle tone. The reason for such cell loss remains unknown but appears to be autoimmune in nature.

Cataplexy is a sudden, brief loss of voluntary muscle tone triggered by fatigue or strong emotions such as laughter, excitement, or fear that occurs during waking hours. During a mild attack, there may be a barely visible weakness in a muscle, such as drooping of the eyelids. The duration of an attack is brief, generally lasting anywhere from a few seconds to a few minutes (usually less than 2 minutes) followed by a rapid return of normal muscle tone and function. More severe episodes may involve a total body collapse. During an episode of cataplexy, an individual is awake but temporarily paralyzed.

The condition is most commonly associated with narcolepsy and can occur after suddenly stopping antidepressant medication. It also occurs with other disorders such as Niemann-Pick type C disease, Prader-Willi

syndrome, Wilson's disease, other medical conditions including stroke, multiple sclerosis, head injury and encephalitis.

Oxybates are central nervous system depressants that reduce EDS and cataplexy in patients with narcolepsy. The precise mechanism by which they produce an effect on cataplexy is unknown. Xyrem has a high salt content. A 3-gram dose contains 550 mg of sodium.

Oxybates, when used in the treatment of narcolepsy, are classified as a Schedule III controlled substances by Federal law. Sodium oxybate or gamma-hydroxybutyrate (GHB) is an endogenous compound and a metabolite of the neurotransmitter gamma-aminobutyric acid (GABA). GHB is listed in the most restrictive schedule (Schedule I) of the Controlled Substances Act.

Oxybates are available only through a restricted distribution program called Risk Evaluation and Mitigation Strategies (REMS), that uses a centralized pharmacy that is specially certified and requires the provider and patient be enrolled into the program. Only providers and centralized pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or potentially serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

The REMS Program provides educational materials to the prescriber and the patient explaining the risks and proper use of sodium oxybate and calcium, magnesium, potassium, sodium oxybates, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The REMS Program also ensures patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Oxybates REMS items:
Enrollment and agreement information
Treatment initiation information
Treatment maintenance information
Pharmacy requirements and responsibilities
Counseling on serious risks and safe use

Cataplexy:
Sudden loss of muscle tone triggered by strong emotions (fear, surprise, joking or laughing); this is transient (less than 2 minutes); symptoms may involve the entire body, or only the knees, neck, or face

Epworth Sleepiness Scale (ESS):
The ESS subjectively measures sleepiness as it occurs in ordinary life situations

Can be used to screen for excessive sleepiness or to follow a subjective response to an intervention
The ESS can be performed in the examination room or waiting room
It is relatively simple and generally takes only a few minutes to complete
It should be repeated at subsequent visits to assess for change
A questionnaire describes eight situations:
- Sitting and reading
- Watching television
- Sitting inactively in a public place
- Riding as a passenger in a car for one hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking with someone
- Sitting quietly after lunch without alcohol
- Sitting in a car as the driver, while stopped for a few minutes in traffic

Each situation receives a score of 0-3, which relates to the likelihood that sleep will be induced:
- 0 = would never doze
- 1 = slight chance of dozing
- 2 = moderate chance of dozing
- 3 = high chance of dozing

The total ESS score ranges from 0-24, with higher scores correlating with increasing degrees of sleepiness
- A score > 10 is consistent with excessive sleepiness

SOREMP:
REM sleep that occurs within 15 minutes of sleep onset

Polysomnography (PSG):
An objective measure of nighttime physiology; it is a test that records sleep architecture (the amount of NREM and REM sleep, number of arousals) and a variety of body functions during sleep, including breathing patterns, heart rhythms and limb movements

Interpreting PSG testing results:

Normal sleep:

Sleep stages cycle in periods alternating throughout the night in intervals of approximately 90-110 min
SOREMP usually absent
4-5 cycles of REM and NREM sleep during a night

Sleep suggestive of Narcolepsy:

Amount of Stage 1 sleep increased
One or more SOREMP present
Disruption of normal sleep pattern with frequent awakenings

Multiple Sleep Latency Test (MSLT):
An objective measurement of daytime physiology that assess the ability or tendency to fall asleep (as indicated by mean sleep latency, or time to sleep onset) during normal waking hours

MSLT is the tendency to fall asleep
It tests for excessive daytime sleepiness (EDS) by measuring how quickly one falls asleep in a quiet environment during the day

- EDS occurs when you are sleepy when you should be awake and alert

MSLT is the standard tool used to diagnose narcolepsy and idiopathic hypersomnia
MSLT is a full-day test that consists of five scheduled naps separated by two-hour breaks
During the MSLT

- Lying flat in bed for the MSLT
- Instructed to lie quietly, assume a comfortable position, keep eyes closed, and try to fall asleep
- The test will measure how long it takes for to fall asleep
- You will be awakened after sleeping 15 minutes
- If you do not fall asleep within 20 minutes, the nap trial ends

Interpreting MSLT testing results:
Normal sleep:
Mean sleep latency of > 10 min
SOREMP usually absent
Narcolepsy:
Mean sleep latency of 8 min or less
Two or more SOREMP present (A SOREMP on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT)

Maintenance of Wakefulness Test (MWT):
MWT is the ability to stay awake
It objectively measures the ability of an individual to remain awake for a defined period of time
It is based on the premise that individuals with a greater degree of sleepiness are less likely to remain awake than individuals with less sleepiness

- MWT may be used to assess an individual's response to therapy

It is the direction of change, not the degree of change, that is meaningful
During the MWT:

- Sit in a recumbent position
- Instructed to sit still and try to remain awake for as long as possible
- Look directly ahead and do not look directly at the light
- Avoid extraordinary measures to stay awake (e.g., slapping the face, singing)
- A session is ended after unequivocal sleep, or after 40 minutes if sleep does not occur
- Sleep is considered unequivocal after three consecutive periods of stage 1 sleep or one period of any other stage of sleep
- For each session, the sleep latency is recorded
- It is documented as being 40 minutes if the patient does not fall asleep
- This is repeated every two hours, until the patient has completed four sessions

The primary measure from the MWT is the mean sleep latency
Healthy individuals who complete four 40-minute protocol sessions, the mean sleep latency is approximately 30 minutes, with > 97% of individuals having a mean sleep latency of ≥ 8 minutes

- A mean sleep latency of < 8 minutes is generally considered abnormal
- Staying awake for at least 40 minutes during all four sessions is strong objective evidence that an individual can stay awake
- A mean sleep latency between 8 and 40 minutes has uncertain significance

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Hypocretin-1 Concentration:

An objective measurement of hypocretin-1 concentration, measured by immunoreactivity, in the cerebrospinal fluid (CSF). This requires a lumbar puncture (spinal tap) procedure.

Interpreting value results:

Normal:

110 pg/mL OR > 1/3 of mean values obtained in normal subjects with the same standardized assay

Narcolepsy Type 1 (with cataplexy):

≤ 110 pg/mL OR < 1/3 of mean values obtained in normal subjects with the same standardized assay

Narcolepsy Type 2 (without cataplexy):

> 110 pg/mL OR > 1/3 of mean values obtained in normal subjects with the same standardized assay

Resources:

Xyrem (sodium oxybate) oral solution product information, revised by Jazz Pharmaceuticals, Inc. 04-2023, at DailyMed http://dailymed.nlm.nih.gov. Accessed August 23, 2024.

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Maski K, Trotti LM, Kotagal S, et al: Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895–1945. Available at https://doi.org/10.5664/jcsm.9326. Accessed October 16, 2023. Re-evaluated September 17, 2024.