COLLEGE OF PHARMACY
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UTAH MEDICAID DUR REPORT
FEBRUARY 2024

PERSISTENCE ON SUBLOCADE (BUPRENORPHINE EXTENDED-RELEASE INJECTION) FOR OPIOID USE DISORDER:
A RETROSPECTIVE REVIEW

Report finalized: January 2024
Report presented: February 2024

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ABBREVIATIONS

ASAM	American Society of Addiction Medicine
CDC	Centers for Disease Control and Prevention
CQMC	Core Quality Measures Collaborative
DSM-5-TR	Diagnostic and Statistical Manual of Mental Disorders 5th Edition-Text Revision
ER	Extended release
FDA	United States Food and Drug Administration
FFS	Fee-for-Service
HCPCS	Healthcare Common Procedure Coding System
ICD	International Classification of Diseases
MOUD	Medications for opioid use disorder
NDC	National Drug Code
NQF	National Quality Forum
OUD	Opioid use disorder
PDL	(Utah Medicaid) Preferred Drug List
SAMHSA	Substance Abuse and Mental Health Services Administration
S-ERBI	Sublocade extended-release buprenorphine injection
SubQ	Subcutaneous
US(A)	United States (of America)

1.0 INTRODUCTION

Opioid use disorder (OUD) is a chronic biopsychosocial addiction disorder associated with mortality rates 6-to-20-fold higher than the general population.[1] Agents whose misuse can lead to OUD include both prescription and non-prescription opioids (eg, heroin).[1] Annual death rates from an opioid overdose have increased in recent decades in the United States (US), with a sharp increase since 2013 that is attributed to synthetic non-methadone opioids, such as fentanyl.[2] As of 2018, approximately 4% of the US adolescent and adult population has misused opioids, and 2 million people have been diagnosed with OUD.[3]

According to criteria from the Diagnostic and Statistical Manual of Mental Disorders 5th Edition-Text Revision (DSM-5-TR), diagnosis of OUD is based on significant functional impairment in association with the presence of at least 2 of 11 symptoms within a 12-month period. Symptoms of OUD can be grouped into impaired control (eg, cravings for opioids or unsuccessful attempts to reduce use), impaired social activity (eg, unreliability at work), risky use behaviors (eg, use despite physical harm), and pharmacologic criteria (ie, tolerance to opioids or withdrawal symptoms upon stopping opioid use). Generally, OUD severity is measured by the number of symptoms. The presence of 4-5 symptoms may be considered moderate, while 6 or more symptoms is considered severe.[1]

OUD is treatable with psychosocial and/or medication treatments.[3] Medications for OUD (MOUD), including methadone, buprenorphine, or naltrexone, are an important cornerstone of therapy to reduce the risk of overdose and death.[3] However, according to a nationally representative survey of US adults in 2021, only approximately 20% of adults with past-year OUD accessed a MOUD, with even lower utilization among some subgroups (eg, Black adults, women, people living in rural areas).[4]

Maintenance pharmacotherapy with MOUD, including methadone, buprenorphine (as buprenorphine extended-release [ER] or other formulations), buprenorphine/naloxone, or naltrexone (with the long-acting injectable preferred) is recommended for all patients with OUD by the 2020 American Society of Addiction Medicine (ASAM) guideline.[3] Methadone, buprenorphine, and naltrexone decrease opioid cravings by addressing part of the pathophysiology driving the addiction. Each agent is available in multiple formulations (see list in **Appendix A**), with naltrexone and buprenorphine each having a long-acting injectable formulation. The ASAM encourages combination treatment with an MOUD plus psychosocial therapy, but medication initiation should not be delayed if psychosocial therapy is unavailable (eg, accessibility issues, patient declines therapy). Importantly, treatment with an MOUD may continue indefinitely. Limited research suggests that treatment durations less than 90 days may be of limited effectiveness, and that longer treatment durations may improve outcomes.[3]

The **objective** of this data-driven report is to use Utah Medicaid claims data to characterize Sublocade ER buprenorphine injection (S-ERBI) therapy persistence (ie, time with continued use) among Utah Medicaid Fee-for-Service (FFS) patients with a diagnosis of OUD who initiate treatment. S-ERBI is a long-acting injectable MOUD that is indicated by the US Food and Drug Administration (FDA) for the treatment of moderate to severe OUD in combination with counseling and psychological support. It should be administered by a healthcare provider monthly (minimum of 26 days between doses), although occasional delays of up to 2 weeks may not impact its effectiveness.[5] Refer to **Table 1** for an overview of S-ERBI therapy.

Table 1. Overview of S-ERBI Indication and Dosing[5]

Description	Buprenorphine is a partial mu-opioid receptor agonist and schedule 3 controlled substance.
FDA Indication	Treatment of moderate to severe OUD, in combination with counseling and psychosocial support • To be started after induction with 8-24 mg/day of transmucosal buprenorphine for ≥ 7 days
Dosing	Buprenorphine 100-300 mg subQ monthly (minimum of 26 days between doses), administered by a healthcare provider (dispensed directly as part of a REMS program). • Initiation dose: 300 mg subQ monthly for 2 months • Maintenance dose: 100 mg subQ monthly, or 300 mg subQ monthly for patients with an insufficient response to 100 mg who tolerated the lower dosage • The typical maintenance administration schedule may occasionally be replaced with 300 mg subQ every 2 months to accommodate certain clinical scenarios (eg, extended travel)
Missed dose	• Administer the missed dose as soon as possible • "Occasional delays in dosing up to 2 weeks are not expected to have a clinically significant impact on treatment effect" (page 4 of package insert recommended dosing section)

Abbreviations: FDA, United States Food and Drug Administration; mg, milligrams; OUD, opioid use disorder; REMS, Risk Evaluation and Mitigation Strategy; S-ERBI, Sublocade extended-release buprenorphine injection; subQ, subcutaneous

S-ERBI is one of two ER buprenorphine subcutaneous injectables indicated for treatment of moderate to severe OUD in the US; the other product is Brixadi, which was only recently approved by the FDA in May 2023.[5-7] Due to a particular interest in S-ERBI persistence, we assessed S-ERBI utilization only, despite the similarities between these ER buprenorphine products.

S-ERBI is a *Carve-Out* medication covered by the Utah Medicaid FFS benefit.[8] As of January 2024, preferred MOUDs on the Utah Medicaid Preferred Drug List (PDL) include buprenorphine ER injection (as Brixadi weekly or monthly, as well as S-ERBI), buprenorphine, buprenorphine/naloxone tablet or film, naltrexone tablet, and long-acting naltrexone.[9] S-ERBI is limited to patients 16 years or older and requires at least 26 days between treatments. [9]

2.0 METHODS

Background information about OUD and S-ERBI therapy were collected from focused searches of the following resources:

- Drugs at FDA: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
- Centers for Disease Control and Prevention (CDC): CDC.gov
- American Society of Addiction Medicine (ASAM): https://www.asam.org/
- DSM-5-TR online textbook: https://www.appi.org/Products/DSM-Library/Diagnostic-and-Statistical-Manual-of-Mental-Di-(1)

2.1 Data Collection and S-ERBI Persistence Calculations

We utilized Utah Medicaid FFS inpatient and outpatient pharmacy and medical claims between March 1, 2021, and February 28, 2023[*] to identify people who had been diagnosed with OUD, initiated S-ERBI therapy, persisted on S-ERBI therapy, and switched to an alternative MOUD. See **Table 2** for definitions of these populations.

We calculated persistence (ie, time with continued S-ERBI use) among adults ages 18 or older who initiated S-ERBI therapy, allowing for 3 S-ERBI treatment gap scenarios. Allowed treatment gaps were defined as the maximum number of additional days between scheduled monthly S-ERBI doses that we would allow while still to maintain a classification of *persistence*, including 7 days (scenario 1), 14 days (scenario 2), or 30 days (scenario 3). For each treatment gap scenario, we determined persistence at S-ERBI treatment lengths of 2-4, 6, 9, and 12 months.

S-ERBI persistence was calculated at the patient level and at the S-ERBI regimen level for each treatment gap allowance scenario and S-ERBI treatment length. S-ERBI regimens are unique S-ERBI treatment courses, defined as a new S-ERBI claim occurring after a lack of S-ERBI claims for at least 2 (for the 7-day and 14-day treatment gaps) to 3 (for the 30-day treatment gap) preceding months. When considering persistence at the patient level, only the first treatment course was counted; when considering persistence at the regimen level, a patient with multiple treatment courses was counted more than once.

S-ERBI persistence rates were calculated by dividing the number of patients or S-ERBI regimen persisters (see definitions in Table 2) by the total number of patients or S-ERBI regimens with enough follow-up time to assess persistence. For example, for scenario 1 with an allowed treatment gap of 7 days and for persistence at 2 treatment months, patients must have had continuous Medicaid eligibility for at least 76 days (ie, accounting for 31 days between monthly S-ERBI administrations [× 2] + up to a 7-day gap in therapy [×2]) to be included in the denominator. See **Table 3** for information about how S-ERBI persistence was calculated.

In addition to calculating S-ERBI persistence, we assessed the proportions of patients (or S-ERBI regimens) with sufficient follow-up time for each designated number of S-ERBI treatment months who switched to another MOUD rather than continuing S-ERBI. We looked for switches to other medications recognized as maintenance therapy options in the 2020 ASAM guideline (see list in Appendix A).[3]

[**] The timeframe from March 2021 to February 2023 was chosen because it was the most recent two-year period with complete Utah Medicaid claims data available at the time of starting this project.

Table 2. Definitions of Populations Identified from Utah Medicaid FFS Claims Data[a]

Population	Definition
OUD diagnosis	Adults (aged ≥ 18 years) with ≥ 1 Medicaid FFS claim for an ICD-10 code related to abuse or misuse of opioids (F11.XX) between 3/1/2021 and 2/28/2023.
S-ERBI initiator	Patients with ≥ 1 Medicaid FFS claim for S-ERBI (assessed by NDC code) with an OUD diagnosis between 3/1/2021 and 2/28/2023.
S-ERBI persister	Patients meeting criteria for OUD diagnosis and S-ERBI initiation with continuous Medicaid eligibility from the date of the first S-ERBI claim to the month after the last S-ERBI claim, and sufficient continuous follow up time (variable depending on allowed treatment gap) to assess persistence for 2, 3, 4, 6[b], 9, and 12 S-ERBI treatment months. See Table 3 for details of how S-ERBI persistence was calculated. • We assessed persistence using 3 different scenarios, or allowances for gaps in therapy: 7 days[b] (consistent with the "Continuity of Pharmacotherapy for OUD" clinical quality measure), 14 days, and 30 days. • S-ERBI persistence was calculated for unique patients and by S-ERBI regimen, defined as a S-ERBI initiation without a S-ERBI claim within the previous 2 months for the 7-day and 14-day treatment gaps or within the previous 3 months for the 30-day treatment gap.
OUD therapy switcher	S-ERBI persisters without a claim for S-ERBI within the allowed treatment gap who instead have a claim (NDC[c] or HCPCS[d] as listed in Appendix A) for at least 1 alternative MOUD within the designated treatment gap (ie, 7, 14 or 30 days) instead of S-ERBI. Assessed only among patients with sufficient follow-up to complete the treatment length (ie, 2-4, 6, 9, and 12 treatments) and without discontinuing S-ERBI treatments through all but the final treatment period length (eg, assessed switches after 8 treatments for patients with enough follow-up to complete 9 treatments). • Allowed alternative MOUD includes non-S-ERBI buprenorphine, buprenorphine/naloxone, and methadone products indicated for treatment of OUD.

Abbreviations: FFS, Fee-for-Service; HCPCS, Healthcare Common Procedure Coding System; ICD, International Classification of Diseases; MOUD, medications for opioid use disorder; NDC, National Drug Code; OUD, opioid use disorder; S-ERBI, Sublocade extended-release buprenorphine injection

[a] *Assessed using inpatient and outpatient Utah Medicaid FFS claims between 3/1/2021 and 2/28/2023*

[b] *Consistent with methods/definitions used by the Core Quality Measures Collaborative (CQMC) measure for "Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)." Six months of persistence (allowing for a 7-day gap in therapy) is the target for this measure.*[10]

[c] *We used NDC codes for these products identified from the Utah Medicaid American Hospital Formulary Service reference table in December 2023. Included products recommended for OUD treatment by the 2020 ASAM guideline,*[3] *and not products indicated for pain (eg, buprenorphine sublingual tablets not weekly patches).*

[d] *In accordance with the guidance from the CQMC for "Continuity of Pharmacotherapy for Opioid Use Disorder" measure, methadone claims were limited to the HCPCS code since it is only dispensed for OUD treatment in licensed facilities.*[10]

Table 3. S-ERBI Persistence Rate Calculation

Overall Calculation *Calculated at the patient or S-ERBI regimen level by dividing the numerator by the denominator at each treatment gap scenario (ie, 7, 14, or 30 days) and treatment length.* *Reported as a percentage of those eligible (with sufficient follow-up time for the number of treatment(s)).*	
Numerator	Number of unique patients or S-ERBI regimens meeting criteria for S-ERBI persister (see Table 2) using the designated allowed treatment gap with sufficient follow up for the number of S-ERBI treatment months assessed.
Denominator	Number of unique patients or S-ERBI regimens who initiated S-ERBI (met criteria for S-ERBI initiator in Table 2) and had sufficient follow up for the number of treatment months assessed.
Calculation of Treatment Gap Allowance and Required Follow-up Length	
Allowed treatment gap	To meet criteria for S-ERBI persistence, patients must have had successive S-ERBI claims within the allowed treatment gap length. • Gaps in therapy were added to a 31-day maximal treatment length for monthly S-ERBI therapy. The following is the maximal number of days allowed between S-ERBI claim codes for a 7-day gap (scenario 1), 14-day gap (scenario 2), and 30-day gap (scenario 3): 38 days, 45 days, and 61 days, respectively.
Follow-up length	Patients in the numerator and denominator at each treatment follow-up length must have had continuous Utah Medicaid eligibility for the length of time necessary to calculate persistence, as determined by the following equation: • ((31 x number of treatments) + (gap length x number of S-ERBI treatment months))

Abbreviations: S-ERBI, Sublocade extended-release buprenorphine injection

Our definition of S-ERBI persistence is extrapolated from the "Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)" clinical quality measure hosted by the University of Southern California and endorsed by the Core Quality Measures Collaborative (CQMC)[†] as of June 2017[11] (last updated in November 2021).[12] It reports the percentage of adults on any OUD pharmacotherapy for at least 180 days, allowing up to a 7-day gap in therapy to maintain persistence. The quality measure also measures 6 months of continuous persistence, which is the typical maximal clinical trial length in pivotal trials leading to FDA approval of MOUD.[10]

Notably, we did not include switches to lower-dose formulations of buprenorphine that are FDA-indicated for pain (eg, buprenorphine transdermal patches[13]). We are aware of observational evidence (primarily from case reports) of buprenorphine "micro-induction" that involves starting low-dose buprenorphine before withdrawal from other opioids with the goal of improving access to buprenorphine maintenance therapy for OUD.[14] Buprenorphine formulations not FDA-approved for OUD have been used in micro-inductions,[14] but this is generally a short-term therapy (eg, <10 days). Since our definition of MOUD switchers allows for up to a 30-day gap, we would likely capture most MOUD switches even if the patient completed a “micro-induction” with a low-dose buprenorphine

[†] Prior to March 2023, the CQMC had a partnership with the National Quality Forum (NQF) as the consensus-based entity for the US Centers for Medicaid and Medicaid Services (CMS), and this measure was called “NQF3175.” Definitions for NQF3175 match those for CBE 3175, now housed by the Partnership for Quality Measurement.

product (not captured in our definition) before starting a guideline-recommended MOUD (agent captured in our definition).

3.0 S-ERBI UTILIZATION

During the target period (between March 1, 2021, and February 28, 2023), 16,941 Utah Medicaid patients had a claim for a diagnosis of opioid abuse or misuse. Of patients with an opioid abuse or misuse diagnosis, as determined by a claim with the ICD-10 F11.XX diagnosis, 1,310 patients (approximately 7.7%) also had a claim for S-ERBI. See **Appendix B** for an overview of how patients among the Utah Medicaid FFS population were selected for inclusion for calculating S-ERBI persistence and switches to another recognized MOUD.

In the following sections, we summarize persistence on S-ERBI and the proportion of eligible patients who switched to another MOUD.

3.1 S-ERBI Persistence

Table 4 shows persistence rates on S-ERBI for 2, 3, 4, 6, 9 and 12 treatments, by patient, allowing for 3 different gaps (ie, 7, 14, and 30 days) between S-ERBI treatments to maintain persistence. For each allowed S-ERBI treatment gap, persistence steadily declines as the number of treatments increase. At the shortest length of 2 observable S-ERBI treatment months[‡], patient persistence rates range from 65.9% to 75.1% with an allowed 7-day and 30-day treatment gap, respectively. By 12 treatments, fewer than 20% of patients are persistent, with estimates ranging from 7.6% (7-day gap) to 19.2% (30-day gap). For each treatment duration, persistence rates are highest using the largest allowed treatment gap of 30 days.

We also calculated persistence by S-ERBI regimen, which is each S-ERBI initiation with at least a 2-month (for the 7-day or 14-day treatment gap) or 3-month (for the 30-day treatment gap) preceding period without a S-ERBI claim. See **Appendix C** for S-ERBI persistence results by S-ERBI regimen. For each treatment duration, there were slightly more S-ERBI regimens than unique patients, suggesting that some patients restart S-ERBI therapy. For example, there are 807 unique patients with sufficient Medicaid membership time to receive 6 S-ERBI treatments compared to 977 S-ERBI regimens. Trends in S-ERBI persistence rates by S-ERBI regimen are consistent with the patient level results.

[‡] Because the actual length of time to maintain persistence differed by treatment gap scenario, the minimum number of observable treatment months is used to express persistence duration.

Table 4. Patient-level S-ERBI Persistence Rates Over a Range of Possible Treatment Durations for 3 Different Gap Allowance Scenarios

Minimum number of observable treatment months[a]	Scenario 1: 7-day treatment gap allowance (≤ 38 days allowed between treatments to maintain persistence)		Scenario 2: 14-day treatment gap allowance (≤ 45 days allowed between treatments to maintain persistence)		Scenario 3: 30-day treatment gap allowance (≤ 61 days allowed between treatments to maintain persistence)	
	Observable patients Patients with sufficient follow-up time (N)	**Persistent patients** n (%) out of all observable patients	**Observable patients** Patients with sufficient follow-up time (N)	**Persistent patients** n (%) out of all observable patients	**Observable patients** Patients with sufficient follow-up time (N)	**Persistent patients** n (%) out of all observable patients
2	1017	670 (65.9%)	1011	714 (70.6%)	991	744 (75.1%)
3	976	464 (47.5%)	956	513 (53.7%)	904	534 (59.1%)
4	916	303 (33.1%)	881	347 (39.4%)	818	363 (44.4%)
6	807	161 (20.0%)	770	196 (25.5%)	677	211 (31.2%)
9	682	69 (10.1%)	601	91 (15.1%)	467	102 (21.8%)
12	540	41 (7.6%)	455	53 (11.6%)	224	43 (19.2%)

Abbreviations: ICD, International Classification of Diseases; N, number (count); S-ERBI, Sublocade extended-release buprenorphine injection

[a] Minimum number of observable treatment months is the minimum duration of time over which a patient would need to be observable in order to rule out that they had persisted with the specified number of monthly treatment cycles, allowing for each treatment gap allowance. Because we explored 3 different gap allowances, observation times varied across each of the 3 scenarios.

Note: All included patients were unique patients with continuous Utah Medicaid eligibility for the entire minimum number of potential treatment months length who had at least 1 claim for an opioid abuse/misuse diagnosis (ICD-10 'F11.xx') and at least 1 S-ERBI claim.

3.2 Switches to Another Opioid Use Disorder Medication

To identify whether patients who discontinued S-ERBI switched to another MOUD, we calculated the proportions of patients with a claim for a second OUD therapy (see list of allowed MOUD in Appendix A) within the allowed treatment gap (**Table 5).** Overall, few patients who discontinued S-ERBI switched to an alternative MOUD. The highest proportion of patients who switched therapies occurred after 1 S-ERBI treatment. The proportions of patients switching therapies declined as the number of S-ERBI treatments increased. See **Appendix D** for a summary of the number of switches to another MOUD per S-ERBI regimen, which shows similar trends.

Table 5. Frequencies and Percentages of Patients Who Switched from S-ERBI to Other OUD Maintenance Therapies,[a] according to 3 different Treatment Gap Allowance Scenarios

Number of S-ERBI treatment months preceding each switch[b]	Patients[c] switched by treatment gap allowance, n (%) of patients with enough follow-up time for the number of treatments		
	Scenario 1 7 days	**Scenario 2** 14 days	**Scenario 3** 30 days
1	105 (10.3%)	110 (10.9%)	114 (11.5%)
2	47 (4.8%)	51 (5.3%)	56 (2.6%)
3	41 (4.5%)	44 (5.0%)	38 (4.6%)
5	8 (1.0%)	11 (1.4%)	12 (1.8%)
8	6 (0.9%)	7 (1.2%)	7 (1.5%)
11	<5 (<0.9%)	<5 (<1.1%)	<5 (<2.2%)

Abbreviations: FDA, United States Food and Drug Administration; OUD, opioid use disorder; N, number (count); S-ERBI, Sublocade extended-release buprenorphine injection

[a] Includes therapies other than S-ERBI recommended by the American Society of Addiction Medicine for OUD treatment maintenance therapy,[3] including other buprenorphine formulations, buprenorphine/naloxone, and naltrexone. See Appendix A for list of other pharmacotherapies for OUD.

[b] Switches were calculated among patients with sufficient follow-up time who did not persist at S-ERBI after the measured number of treatments. For example, patients switched after 1 treatment are among those with sufficient follow-up for at least 2 treatments.

[c] Patients are unique patients with continuous Utah Medicaid eligibility for the entire persistence length who had at least 1 claim for an opioid abuse/misuse diagnosis (ICD-10 code of 'F11.xx') and at least 1 S-ERBI claim.

4.0 DISCUSSION AND SUMMARY

Opioid use disorder (OUD) is a chronic addiction disorder that increases the risk of death from an opioid overdose or other cause.[1] Sublocade extended-release [ER] buprenorphine injection (S-ERBI) is a monthly injectable therapy indicated in combination with psychosocial treatments (eg, psychotherapy, counseling) for the treatment of moderate to severe OUD.[5] It is one of several medications for OUD (MOUD), recommended by the American Society of Addiction Medicine (ASAM) as maintenance therapy for OUD.[3] The optimal duration of treatment with S-ERBI is not specifically defined, but available evidence suggests that long-term use of S-ERBI (or another MOUD) improves treatment outcomes.[3] Adherence to MOUD is also associated with lower healthcare costs.[15-17] MOUD treatment continuity for 6 months is used as a clinical quality outcome measure, selected based on the duration of pivotal clinical trials for many MOUD.[10-12]

This report provides a descriptive analysis of persistence on S-ERBI therapy for up to 12 treatments in a cohort of Utah Medicaid patients. Our claims-based descriptive analysis of Utah Medicaid FFS utilization suggests that many patients are not achieving the minimal benchmark S-ERBI therapy durations of 3 or 6 months.[3,12] For the period of March 1, 2021 to February 28, 2023, only 20% of patients (using the most restrictive gap of 7 days) with continuous Medicaid eligibility who initiated S-ERBI persisted (ie, continued) for 6 treatments. Even when up to a 30-day gap between S-ERBI treatments is allowed, the proportion of patients persistent for 6 treatments only increases to 31%.

In our cohort, early treatment discontinuations after the first or second S-ERBI dose was common. Only approximately 75% of eligible patients received the second dose and 60% received a third dose, even when allowing for up to a 30-day treatment gap between S-ERBI doses. Relatively few patients who discontinued S-ERBI switched to an alternative, ASAM-recognized MOUD maintenance therapy (ie, other buprenorphine formulations, buprenorphine/naloxone, naltrexone, or methadone).

Persistence on S-ERBI in our cohort of Utah Medicaid FFS patients appears comparable to or worse than rates reported in the medical literature,[18-20] although persistence rates in other studies have been calculated using different methods, thereby limiting direct comparability. For example, in one study, the 180-day buprenorphine (any OUD formulation) retention rate was approximately 22% each month from January 2016 to January 2022 using claims from an all-payer US database.[18] In a cohort of commercially insured US patients, 50% of patients who initiated buprenorphine ER discontinued treatment by 3 months, compared with about 53% in our cohort (allowing for a 7-day treatment gap).[20] Higher retention rates have been reported using a cohort in Canada, and in clinical trials.[19]

Relapses are an expected part of OUD recovery. Multiple treatment attempts may be required for long-term treatment success.[21] We also assessed persistence per S-ERBI regimen, which includes any S-ERBI start without S-ERBI utilization in the prior 2 months. Persistence by S-ERBI regimen was shown to be numerically similar or modestly worse than persistence by patient. For example, regimen persistence for 6 treatments (allowing for a 7-day treatment gap) is 16.7%, compared to 20% by patient. Comparison of persistence rates allowing for a 7-day versus 30-day gap in therapy also shows higher persistence with a 30-day treatment gap at all measured treatment durations (ie, 2, 3, 4, 6, 9 and 12 months). The fact that persistence rates are higher when allowing a longer gap between S-ERBI doses could be due to many different factors. For example, due to barriers in receiving the S-ERBI dose on schedule such as the

patient having to travel a long distance to receive S-ERBI; however, this is speculatory without additional research. Collectively, this suggests that some patients are returning to S-ERBI therapy after longer treatment gaps, which is encouraging for long-term recovery. Nonetheless, frequent gaps in S-ERBI therapy exceeding 14 days may impair S-ERBI effectiveness.[5]

Since S-ERBI persistence is generally low and many patients discontinue treatment by 3 months, Utah Medicaid may consider identifying ways to encourage and/or facilitate persistence with S-ERBI therapy. The following are some options for next steps:

1. Consider reaching out to patients after the first S-ERBI claim, or at least within the first few months of initiating treatment, to provide education about the importance of adherence in achieving successful outcomes, address any concerns or questions regarding treatment, and/or encourage speaking with their provider to switch to another recommended MOUD if appropriate. Furthermore, it can also serve as an opportunity to reinforce adherence, such as reminding patients of when their next dose of S-ERBI may be administered, and to address any issues to avoid unnecessary delays in therapy.
    - Our descriptive analysis of claims data suggests that nearly half of patients with continued Medicaid coverage who initiate S-ERBI discontinue before receiving 3 doses. Thus, interventions aimed at prompting treatment persistence may be especially beneficial shortly after S-ERBI initiation.
    - Given the observed declines in S-ERBI persistence across up to 12 months of treatment, interventions between the third and twelfth S-ERBI dose could also prove valuable for some patients.
    - Using the higher S-ERBI monthly maintenance dose (300 mg) is an option for patients who have an insufficient response, but tolerated, the lower dosage of 100 mg.[5]
2. Consider consulting additional resources or experts for guidance on evidence-based approaches to promote adherence to S-ERBI or MOUD in general.
    - A systematic search for resources and summary of evidence-based approaches was outside of the scope of this report. A future report could follow up on this topic.
    - We are aware of recent guidance from the Substance Abuse and Mental Health Services Administration (SAMSHA; 2021) and the Centers for Disease Control and Prevention (CDC; 2022), which may provide some guidance:
        - SAMHSA: https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf
        - CDC: https://www.cdc.gov/drugoverdose/pdf/pubs/Linkage-to-Care-Resource-for-Action-508.pdf. The CDC report is devoted to connecting people with OUD to care, and provides examples of how to encourage treatment in different settings.[21] Section 5 of the report identifies barriers and facilitators to treatment,[21] which could be used to guide educational efforts or changes at the insurer level.

Not all factors associated with poor MOUD treatment persistence can be addressed by insurance providers alone. For example, a known barrier to treatment is the challenge of accessing healthcare providers capable of prescribing MOUD that accept the patient's insurance; distance to such providers can exceed 50 miles in areas of lower population density.[21] As part of a multidisciplinary approach to care, incorporating psychosocial treatments with MOUD is encouraged,[3,22] yet many patients may not

access these services.[23] In addition, stigma in the general population and among healthcare providers also present barriers to optimal care for people with OUD.[22,24] Ultimately, it is advisable to consider exploring various factors to improve MOUD treatment persistence.

While this report provides S-ERBI utilization trends, it is crucial to note that claims data may not reflect true utilization due to inherent limitations of the data source. Instances where patients intentionally discontinued S-ERBI after successful treatment were not captured by our analysis. Our analysis was also limited to adults 18 years or older, so it is unknown if persistence rates are similar in pediatric patients. Persistence calculations are only among patients with sufficient Medicaid eligibility for the S-ERBI treatment duration assessed; it is possible that persistence rates would be different if we had a complete cohort of all patients regardless of Medicaid coverage.

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APPENDIX A – LIST OF IDENTIFIED OPIOID USE DISORDER MEDICATIONS AND ASSOCIATED CLAIM CODES

Table A1. Options for OUD Maintenance Pharmacotherapy According to the 2020 ASAM Guideline and Claims Used to Identify OUD Medications[a]

Medication[3] Generic Name **Brand Name(s)[b]**	**Description[3]**	**Claims Codes Used to Identify the Medication**
Buprenorphine Monotherapy Products		
Buprenorphine extended-release **Sublocade**	Injection for subcutaneous use (100 mg/mL, 300 mg/mL)	*NDC codes:* 12496010001, 12496010005, 12496030001, 12496030005
Buprenorphine extended-release **Brixadi**	Injection for subcutaneous use (8 mg, 16 mg, 24 mg, 32 mg, 64 mg, 96 mg, 128 mg)	*NDC codes:* 58284022801, 58284022891, 58284021601, 58284021691, 58284022401, 58284022491, 58284023201, 58284023291, 58284026401, 58284026491, 58284020801, 58284029601, 58284029691
Buprenorphine *Generic*	Sublingual tablet (2 mg, 8 mg)	*NDC codes:* 00054017613, 00093537856, 00121101930, 00228315603, 00378092393, 00904715404, 35356055530, 42858050103, 50383092493, 55700030230, 60687048111, 60687048121, 62756045983, 63629712501, 63629712502, 63629947501, 68308020230, 70518221700, 70518222600, 70518222601, 70518222602, 70518222603, 71335095001, 71335095002, 71335095003, 00054017713, 00093537956, 00121203830, 00228315303, 00378092493, 00904715504, 35356055630, 42858050203, 43063075306, 50090157100, 50090292400, 50383093093, 53217024630, 54569657800, 55700030330, 60687049211, 60687049221, 62756046083, 63629712601, 63629712602, 68258299103, 68308020830, 70518162500, 70518201400, 70518201401, 70518221800, 71335115401, 71335115402, 71335115403, 71335116301, 71335116302, 71335116303, 12496127802, 49999063830, 12496131002, 49999063930, 63629409201, 63874117303
Buprenorphine implant **Probuphine**	Implant for subdermal use (80 mg)	*NDC codes:* 52440010014, 58284010014
		HCPCS codes: J0570
Buprenorphine/Naloxone Combination Products		
Buprenorphine/naloxone *Generic*	Sublingual tablet (2 mg/0.5 mg, 8 mg/2 mg)	*NDC codes:* see NDCs for the sublingual/buccal film (Suboxone) below.
		HCPCS codes: J0571, J0572, J0573, J0574, J0575
Buprenorphine/naloxone **Suboxone**	Sublingual or buccal film (2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg)	*NDC codes:* 00378876816, 00378876893, 00781724906, 00781724964, 43598058101, 43598058130, 47781035803, 47781035811, 50742036501, 50742036530, 52427071203, 52427071211, 00378876516, 00378876593, 00781721606, 00781721664, 43598057901, 43598057930, 47781035503, 47781035511, 52427069203, 52427069211, 00378876616, 00378876693, 00781722706, 00781722764, 43598058001, 43598058030, 47781035603, 47781035611, 52427069403, 52427069411, 00378876716, 00378876793, 00781723806, 00781723864, 43598058201, 43598058230, 47781035703, 47781035711, 50742036401, 50742036430, 52427069803, 52427069811, 00054018813, 00093572056, 00121101830, 00228315403, 00228315473, 00406192303, 00406800503, 00904700906, 16729054910, 42291017430, 42858060103, 50268014411, 50268014415, 50383029493, 55700018430, 55700090130, 60429058630, 60429058633, 60687062611, 60687062665, 62175045232, 62756096983, 63629948201, 65162041603, 70518100700, 71335129601, 00054018913, 00093572156, 00121203630, 00228315503, 00228315567, 00228315573, 00406192403, 00406802003, 00904701006, 16729055010, 42291017530, 42858060203, 50268014511, 50268014515, 50383028793, 51862060830, 53217013830, 54569640800, 60429058730, 60429058733, 60687063711, 60687063765, 62175045832, 62756097083, 63629948301, 65162041503, 70518231100, 70518312900, 70518338900, 71335137801, 71335172501, 71335172502, 71335185801, 71335185802, 12496121201, 12496121203, 12496120201, 12496120203, 12496120401,

Abbreviations: ASAM, American Society of Addiction Medicine; HCPCS, Healthcare Common Procedure Coding System; mg, milligram; mL, milliliter; OUD, opioid use disorder; NDC, National Drug Code;

[a] Assessed using inpatient and outpatient Utah Medicaid FFS claims between 3/1/2021 and 2/28/2023. Eleven-digit NDC codes used include those listed in a table of NDCs by Utah Medicaid. HCPCS codes use are those recommended for the "Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)" clinical quality measure hosted by the University of Southern California and endorsed by the Core Quality Measures Collaborative (CQMC).[8]

[b] Assessed for both brand and generic products when available (NDC codes may reflect both), regardless of whether the Brand product has been discontinued). One brand product for buprenorphine/naloxone per the ASAM guideline (Cassipa) was not included among searched NDCs since it was not among possible products searchable in the Utah Medicaid table of NDCs. . Brand names are given as examples/for reference.

[c] We used NDC codes, not HCPCS codes (Q9991 and Q9992) for Sublocade extended-release buprenorphine injections (S-ERBI) because NDC claims alone identified more than 99% of all S-ERBI utilization (ie, using HCPCS or NDC codes) and the time between S-ERBI claims by NDC code matched the expected cadence of monthly S-ERBI use.

[d] The buprenorphine implant is a recommended option in the 2020 ASAM OUD treatment guideline[3]; however, since October 2020 it has not been available due to a discontinuation by the manufacturer that was unrelated to its safety.[17]

[e] Methadone utilization was assessed using the HCPCS code for administration only, regardless of formulation, in accordance with guidance from the CQMC for the quality measure which recommends against using NDC codes to assess methadone utilization since it might include use for pain.[8]

Table A1. Options for OUD Maintenance Pharmacotherapy According to the 2020 ASAM Guideline and Claims Used to Identify OUD Medications[a]

Medication[3] Generic Name **Brand Name(s)[b]**	**Description[3]**	**Claims Codes Used to Identify the Medication**
		12496120403, 12496120801, 12496120803, 54569639900, 55700014730, 00490005100, 00490005130, 00490005160, 00490005190, 12496128302, 16590066605, 16590066630, 49999039507, 00378876816, 00378876893, 00781724906, 00781724964, 43598058101, 43598058130, 47781035803, 47781035811, 50742036501, 50742036530, 52427071203, 52427071211, 00378876516, 00378876593, 00781721606, 00781721664, 43598057901, 43598057930, 47781035503, 47781035511, 52427069203, 52427069211, 00378876616, 00378876693, 00781722706, 00781722764, 43598058001, 43598058030, 47781035603, 47781035611, 52427069403, 52427069411, 00378876716, 00378876793, 00781723806, 00781723864, 43598058201, 43598058230, 47781035703, 47781035711, 50742036401, 50742036430, 52427069803, 52427069811, 00054018813, 00093572056, 00121101830, 00228315403, 00228315473, 00406192303, 00406800503, 00904700906, 16729054910, 42291017430, 42858060103, 50268014411, 50268014415, 50383029493, 55700018430, 55700090130, 60429058630, 60429058633, 60687062611, 60687062665, 62175045232, 62756096983, 63629948201, 65162041603, 70518100700, 71335129601, 00054018913, 00093572156, 00121203630, 00228315503, 00228315567, 00228315573, 00406192403, 00406802003, 00904701006, 16729055010, 42291017530, 42858060203, 50268014511, 50268014515, 50383028793, 51862060830, 53217013830, 54569640800, 60429058730, 60429058733, 60687063711, 60687063765, 62175045832, 62756097083, 63629948301, 65162041503, 70518231100, 70518312900, 70518338900, 71335137801, 71335172501, 71335172502, 71335185801, 71335185802, 12496121201, 12496121203, 12496120201, 12496120203, 12496120401, 12496120403, 12496120801, 12496120803, 54569639900, 55700014730, 00490005100, 00490005130, 00490005160, 00490005190, 12496128302, 16590066605, 16590066630,49999039507, 49999039515, 49999039530, 52959074930, 54569549600, 54868575000, 63629402801, 63874108503, 68071151003, 68258299903, 12496012832, 12496130602, 16590066705, 16590066730, 16590066790, 23490927003, 23490927006, 23490927009, 35356000407, 35356000430, 43063018407, 43063018430, 52959030430, 54569573900, 54569573901, 54569573902, 54868570700. 54868570701, 54868570702, 54868570703, 54868570704, 55045378403, 63629403401, 63629403402, 63629403403, 63874108403, 66336001630, 68071138003, 12496013062
		HCPCS codes: J0571, J0572, J0573, J0574, J0575
Buprenorphine/naloxone **Zubsolv**	Sublingual tablet (0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg)	NDC codes: 54123090730, 54123091430, 54123011430, 54123092930, 54123095730, 54123098630
		HCPCS codes: J0571, J0572, J0573, J0574, J0575
Buprenorphine/naloxone **Bunavail**	Buccal film (2.1 mg/0.3 mg, 4.2 mg/0.7 mg, 6.3 mg/1 mg)	NDC codes: 59385001201, 59385001230, 59385001401, 59385001430, 59385001601, 59385001630
		HCPCS codes: J0571, J0572, J0573, J0574, J0575
Naltrexone Monotherapy Products		
Naltrexone *Generic*	Oral tablet (50 mg)	*NDC codes:* 52152010504, 52152010510, 52152010550, 00406009201, 00406009203, 00185003901, 00185003930, 00406117001, 00406117003, 00555090201, 00555090202 00904703604, 16729008101, 16729008110, 42291063230, 43063059115, 47335032683, 47335032688, 50090286600, 50090307600, 50090492500, 50436010501, 51224020630 51224020650, 52152010502, 52152010530, 53217026130, 54569672000, 54569913900, 54868557400, 62135024230, 62135024290, 63629104601, 63629104701, 65694010003 65694010010, 68084029111, 68084029121, 68094085362, 68115068030, 68788708401, 68788708402, 68788708403, 68788708409, 68788708460, 00056001130, 00056001170 51285027501, 51285027502

Abbreviations: ASAM, American Society of Addiction Medicine; HCPCS, Healthcare Common Procedure Coding System; mg, milligram; mL, milliliter; OUD, opioid use disorder; NDC, National Drug Code;

[a] Assessed using inpatient and outpatient Utah Medicaid FFS claims between 3/1/2021 and 2/28/2023. Eleven-digit NDC codes used include those listed in a table of NDCs by Utah Medicaid. HCPCS codes use are those recommended for the "Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)" clinical quality measure hosted by the University of Southern California and endorsed by the Core Quality Measures Collaborative (CQMC).[8]

[b] Assessed for both brand and generic products when available (NDC codes may reflect both), regardless of whether the Brand product has been discontinued). One brand product for buprenorphine/naloxone per the ASAM guideline (Cassipa) was not included among searched NDCs since it was not among possible products searchable in the Utah Medicaid table of NDCs. . Brand names are given as examples/for reference.

[c] We used NDC codes, not HCPCS codes (Q9991 and Q9992) for Sublocade extended-release buprenorphine injections (S-ERBI) because NDC claims alone identified more than 99% of all S-ERBI utilization (ie, using HCPCS or NDC codes) and the time between S-ERBI claims by NDC code matched the expected cadence of monthly S-ERBI use.

[d] The buprenorphine implant is a recommended option in the 2020 ASAM OUD treatment guideline[3]; however, since October 2020 it has not been available due to a discontinuation by the manufacturer that was unrelated to its safety.[17]

[e] Methadone utilization was assessed using the HCPCS code for administration only, regardless of formulation, in accordance with guidance from the CQMC for the quality measure which recommends against using NDC codes to assess methadone utilization since it might include use for pain.[8]

Table A1. Options for OUD Maintenance Pharmacotherapy According to the 2020 ASAM Guideline and Claims Used to Identify OUD Medications[a]

Medication[3] Generic Name **Brand Name(s)[b]**	**Description[3]**	**Claims Codes Used to Identify the Medication**
Naltrexone extended-release **Vivitrol**	Injection for intramuscular use (380 mg)	NDC codes: 63459030042, 65757030001
		HCPCS code: J2315
Methadone Products		
Methadone **Methadose**	Oral tablet (5 mg, 10 mg); Dispersible tablet (40 mg); Oral solution (5 mg/5 mL, 10 mg/5 mL); Oral concentrate solution (10 mg/mL)	*HCPCS code[e]:* H0020

Abbreviations: ASAM, American Society of Addiction Medicine; HCPCS, Healthcare Common Procedure Coding System; mg, milligram; mL, milliliter; OUD, opioid use disorder; NDC, National Drug Code;

[a] Assessed using inpatient and outpatient Utah Medicaid FFS claims between 3/1/2021 and 2/28/2023. Eleven-digit NDC codes used include those listed in a table of NDCs by Utah Medicaid. HCPCS codes use are those recommended for the "Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)" clinical quality measure hosted by the University of Southern California and endorsed by the Core Quality Measures Collaborative (CQMC).[8]

[b] Assessed for both brand and generic products when available (NDC codes may reflect both), regardless of whether the Brand product has been discontinued). One brand product for buprenorphine/naloxone per the ASAM guideline (Cassipa) was not included among searched NDCs since it was not among possible products searchable in the Utah Medicaid table of NDCs. . Brand names are given as examples/for reference.

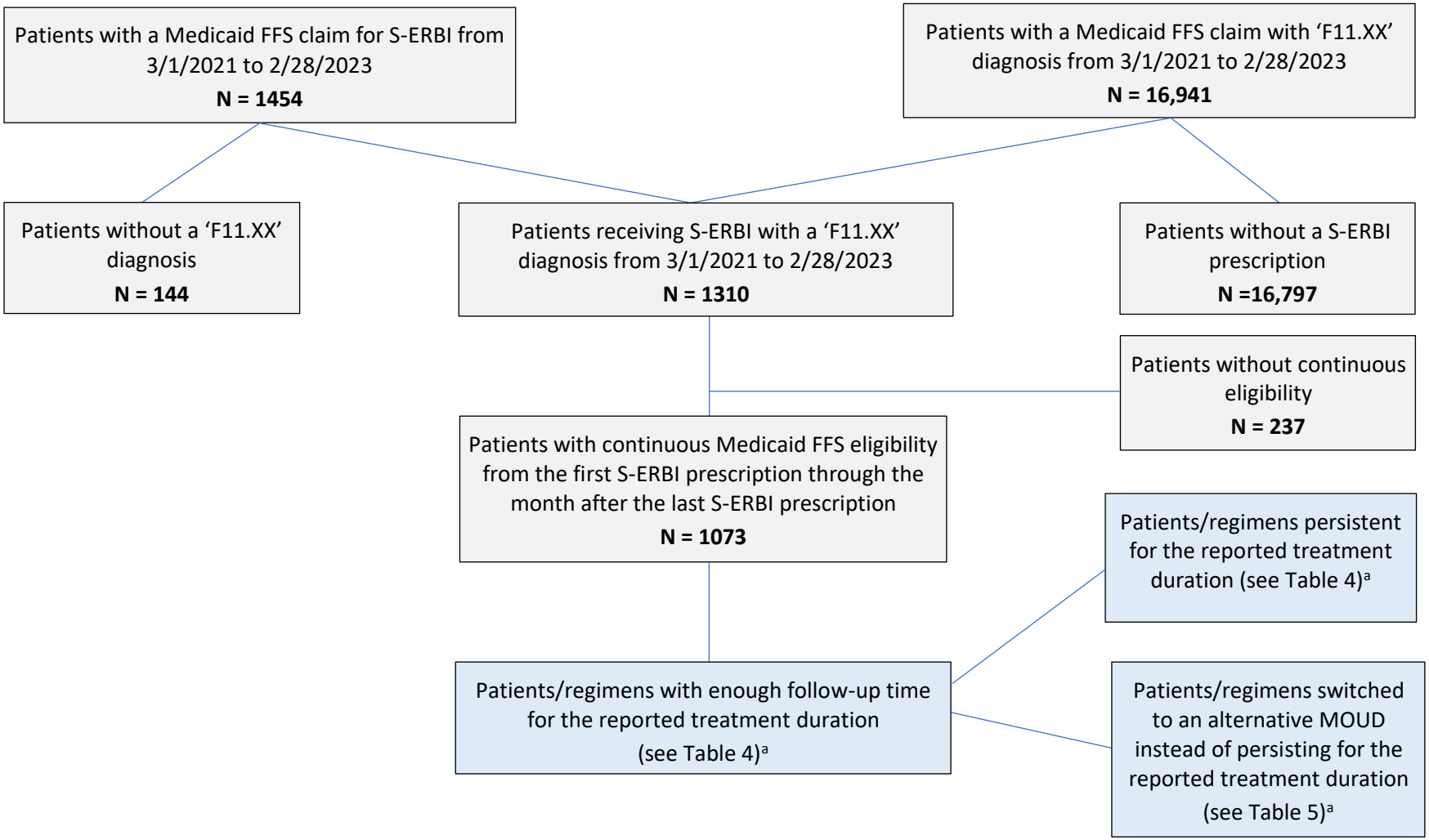
[c] We used NDC codes, not HCPCS codes (Q9991 and Q9992) for Sublocade extended-release buprenorphine injections (S-ERBI) because NDC claims alone identified more than 99% of all S-ERBI utilization (ie, using HCPCS or NDC codes) and the time between S-ERBI claims by NDC code matched the expected cadence of monthly S-ERBI use.

[d] The buprenorphine implant is a recommended option in the 2020 ASAM OUD treatment guideline[3]; however, since October 2020 it has not been available due to a discontinuation by the manufacturer that was unrelated to its safety.[17]

[e] Methadone utilization was assessed using the HCPCS code for administration only, regardless of formulation, in accordance with guidance from the CQMC for the quality measure which recommends against using NDC codes to assess methadone utilization since it might include use for pain.[8]

APPENDIX B – PATIENT COHORT DISPOSITION

The following shows how patients were identified for inclusion for calculating S-ERBI persistence and switches to alternative MOUD.



Abbreviations: FFS, Fee-for-Service; MOUD, medication for opioid use disorder; N, number (count); S-ERBI, Sublocade extended-release buprenorphine injection

[a] Numbers of patients/regimens varied for each blue box. Calculations were performed by allowed gap between S-ERBI claims (7-day, 14-day, or 30-day) and for treatment lengths of 2, 3, 4, 6, 9, and 12.

APPENDIX C – S-ERBI PERSISTENCE BY S-ERBI REGIMEN

Table C1 below shows the results from Table 4 except with persistence calculated per each S-ERBI regimen instead of by patient.

Table C1. Regimen-level S-ERBI Persistence Rates Over a Range of Possible Treatment Durations for 3 Different Gap Allowance Scenarios

Minimum number of observable treatment months[a]	**Scenario 1: 7-day treatment gap allowance** (≤ 38 days allowed between treatments to maintain persistence)		**Scenario 2: 14-day treatment gap allowance** (≤ 45 days allowed between treatments to maintain persistence)		**Scenario 3: 30-day treatment gap allowance** (≤ 61 days allowed between treatments to maintain persistence)	
	Observable regimens Regimens with sufficient follow-up time (N)	**Persistent regimens** n (%) out of all observable regimens	**Observable regimens** Regimens with sufficient follow-up time (N)	**Persistent regimens** n (%) out of all observable regimens	**Observable regimens** regimens with sufficient follow-up time (N)	**Persistent regimens** n (%) out of all observable regimens
2	1292	749 (58.0%)	1278	808 (63.2%)	1143	813 (71.1%)
3	1214	485 (40.0%)	1189	546 (45.9%)	1033	563 (54.5%)
4	1134	314 (27.7%)	1080	364 (33.7%)	926	375 (40.5%)
6	977	163 (16.7%)	911	198 (21.7%)	727	212 (29.2%)
9	772	69 (8.9%)	671	91 (13.6%)	477	102 (21.4%)
12	588	41 (7.0%)	481	53 (11.0%)	224	43 (19.2%)

Abbreviations: ICD, International Classification of Diseases; N, number (count); S-ERBI, Sublocade extended-release buprenorphine injection

[a] *Minimum number of observable treatment months is the minimum duration of time over which a S-ERBI regimen would need to be observable in order to rule out that it had persisted with the specified number of monthly treatment cycles, allowing for each treatment gap allowance. Because we explored 3 different gap allowances, observation times varied across each of the 3 scenarios.*

Note: All included regimens are unique S-ERBI treatment courses, with unique treatments determined by no S-ERBI claims for at least 2 (for the 7-day and 14-day treatment gaps) or 3 (for the 30-day treatment gap) months before a new S-ERBI claim. Regimens may include the same patient more than once.

APPENDIX D – SWITCHES TO AN ALTERNATIVE MOUD BY S-ERBI REGIMEN

Table D1 below shows the results from Table 5 except with switches among S-ERBI regimens instead of by patient.

Table D1. Frequencies and Percentages of Regimens Switched from S-ERBI to Other OUD Maintenance Therapies[a] according to 3 different Treatment Gap Allowance Scenarios

Number of treatments after which the regimen switched[b]	Regimens[c] switched by allowed treatment gap, N (% of patients with enough follow-up time for number of treatments)		
	7 days	14 days	30 days
1 treatment	108 (8.4%)	114 (8.9%)	116 (10.1%)
2 treatments	47 (3.9%)	52 (4.4%)	56 (5.4%)
3 treatments	41 (3.6%)	44 (4.1%)	38 (4.1%)
5 treatments	8 (0.8%)	11 (1.2%)	12 (1.7%)
8 treatments	6 (0.8%)	7 (1.0%)	7 (1.5%)
11 treatments	<5 (<0.9%)	<5 (<1.0%)	<5 (<2.2%)

Abbreviations: FDA, United States Food and Drug Administration; OUD, opioid use disorder; N, number (count); S-ERBI, Sublocade extended-release injection

[a] Includes other therapies recommended by the American Society of Addiction Medicine for OUD treatment maintenance therapy,[3] including other buprenorphine formulations, buprenorphine/naloxone, and naltrexone. See Appendix A for list of other pharmacotherapies for OUD.

[b] Switches were calculated among S-ERBI regimens with sufficient follow-up time who discontinued S-ERBI after the measured number of treatments. For example, S-ERBI regimens switched after 1 treatment are among those with sufficient follow-up for at least 2 treatments.

[c] Regimens are unique S-ERBI treatments, with unique treatments determined by no S-ERBI claims for at least 2 (for the 7-day and 14-day treatment gaps) to 3 (for the 30-day treatment gap) months before a new S-ERBI claim. Regimens may include the same patient more than once.