

Policy Evaluation: Substance Use Disorders

Purpose of the Review:

This goal of this review is to examine the impact of removing prior authorization (PA) requirements for preferred medication assisted therapy (MAT) for treatment of opioid use disorder (OUD).

Research Questions:

1. Has utilization of MAT for OUD increased since removal of PA criteria for preferred MAT products?
2. Did removal of the PA criteria appear to impact rates of long-term, clinical outcomes for patients with OUD (e.g., opioid overdose, use of naloxone, return to opioid use, or concomitant use of MAT and opioids)?
3. Did off-label use of MAT (e.g., for chronic pain or other substance abuse) change after removal of PA criteria?
4. Did utilization of psychosocial support systems change after removal of PA criteria?

Conclusions:

- Utilization of buprenorphine/naloxone and medical claims for MAT continue to increase. After removal of the PA criteria, approximately 83% of patients prescribed MAT had an initial paid claim compared to 40% of patients in the year prior to the PA removal. For patients with paid claims, 40% of the patients had claims for more than 120 days of continuous therapy in the 6 months following the index event (IE), and about 30% of the population had less than 30 days of continuous therapy following their first paid claim.
- After removal of PA criteria, approximately 93% of patients with a denied IE were prescribed products containing only buprenorphine. In 77% of patients, there was a subsequent paid claim for MAT. In the vast majority of patients without a subsequent paid MAT claim, a PA was never requested by the provider.
- Rates of long-term, clinical outcomes were similar before and after removal of the PA criteria.
 - In patients with claims for OUD, paid claims for naloxone have increased from 3.7% to 8.3%. However, 4% of patients prescribed MAT had a subsequent diagnosis of opioid overdose, acute intoxication, or medical claims for naloxone in the 6 months following the index event. More than 90% of these patients did not have a subsequent paid pharmacy claim for naloxone. Less than 1% of patients had 2 or more claims for naloxone.
 - Overall use of opioids was limited following an initial claim for MAT. After MAT initiation, 90-93% of patients had less than 7 days of opioid therapy in the following 6 months. Only 0.7% to 2.2% of patients had more than 30 days of concomitant opioid and MAT use.
- Off-label use of MAT appears to be limited. Approximately 85% of patients had a diagnosis of OUD based on available diagnoses or presence of medical claims for OUD. Rates were similar before and after removal of the PA criteria and upon comparison of patients with paid or denied claims.
- Utilization of non-pharmacological psychosocial support or enrollment in SUD treatment programs was limited. Only 39-40% of patients had at least one claim for non-pharmacological substance use disorder (SUD) services, and approximately 34% of patients had long-term utilization of non-pharmacological therapy after 3 months of treatment with MAT.

Recommendations:

- No PDL or PA criteria changes recommended based on utilization data.

Background:

In January 2017, in order to minimize barriers to care and provide increased access to medications for the treatment of opioid use disorder (OUD), the Pharmacy and Therapeutics Committee recommended removal of PA criteria for naltrexone extended release injection and preferred buprenorphine/naloxone sublingual tablets and film (unless the daily dose of buprenorphine exceeds 24 mg). This recommendation to increase access to treatment for opioid use disorder was part of a larger statewide initiative to address inappropriate opioid use and overdose. For example, in 2016 pharmacists in Oregon became legally able to prescribe naloxone, and in 2017 training requirements for pharmacists prescribing naloxone were removed in order to increase access to the medication. Similarly, starting in late 2016, nurse practitioners and physician assistants could become trained to prescribe and dispense buprenorphine.¹ Ongoing efforts also aim to increase access to behavioral treatments and provide prescribers guidance on medication assisted therapy (MAT) for treatment of OUD.

Upon removal of this PA criteria, several restrictions regarding use of MAT were removed. Previously, PA criteria had restricted buprenorphine use to diagnoses of OUD. Buprenorphine/naloxone is only indicated for OUD, but because it is a partial opioid agonist, it may be prescribed off-label for pain. In addition, with removal of the criteria, patients were no longer required to be enrolled in a treatment program which provides counseling and psychosocial support. Available literature demonstrates that enrollment in a treatment program has been correlated with better long-term outcomes. Removal of PA criteria would effectively increase access to medication treatment for those unable to access other non-pharmacological services, but may also result in less long-term success for patients without non-pharmacological support. Third, members were no longer required to fill their medications at a single pharmacy. In order to discourage concomitant prescribing with opioids, members receiving treatment for opioid use disorder had previously been required to be locked into a single pharmacy. Members who have claims at more than 4 or 5 pharmacies in the past year are still evaluated for the lock-in program, but it is currently unclear if concomitant opioid prescribing has increased since removal of the policy.

Current guidelines from the Veterans Administration and Department of Defense primarily recommend utilization of methadone (in the context of a treatment program), or buprenorphine/naloxone for patients with OUD (strong recommendation).² Buprenorphine alone may be considered for patients who are pregnant (weak recommendation), and extended-release injectable naloxone is recommended as an option for patients for whom opioid agonist therapy is contraindicated, unacceptable, or unavailable, and who have established opioid abstinence for at least 7 days without acute withdrawal symptoms (strong recommendation).²

This goal of this review is to examine the impact of removing PA requirements on preferred products for patients prescribed MAT. Products for OUD which are non-preferred and continue to require PA include Bunavail® (buprenorphine/naloxone film), Probuphine® (buprenorphine implant), buprenorphine sublingual tablets, and Sublocade® (buprenorphine extended-release injection).

Methods:

This is an observational retrospective analysis which compares utilization of treatments for OUD before removal of the PA criteria from preferred products (the control period from 3/1/2016 to 2/28/2017) and after removal of the PA criteria (the experimental period from 3/1/17 to 2/28/18). Drugs for which the PA was removed included preferred buprenorphine/naloxone products and injectable naltrexone (Vivitrol®). The patient population included FFS patients with an opioid use disorder. Patients were excluded if they had Medicare Part D coverage (identified with benefit packages BMM, MBD, MND, or MED) or if they had limited or no Medicaid drug benefit (identified with benefit packages CWM, SMF, SMB). Members were excluded if they were enrolled in Medicaid (based on combined FFS and CCO eligibility) for less than 75% of the time in the year prior to the index event in order to ensure complete medical records for their prior diagnoses. Patients were also required to have continuous Medicaid eligibility in the 3 months after the IE to capture more accurate information for subsequent therapy. Baseline characteristics were assessed at time of the IE.

The following definitions were used to classify groups of interest:

- The **index event (IE)** was defined as the first paid or denied FFS pharmacy claim for MAT. See **Table A1** for codes associated with MAT for opioid use disorder. Claims for MAT included pharmacy claims for buprenorphine/naloxone, buprenorphine, or naltrexone. Denied claims were defined as claims with an error code of 3002 (NDC requires PA), 3000 (units exceed authorized units on PA master file), 4167 (Drug quantity per day limit exceeded), 4026 (day supply limit exceeded for covered NDC), or 2603 (Recipient Locked in) and without any of the error codes listed in **Table A2**. If a patient had a paid and denied claim on the same day, the IE was classified as paid.
- Patients with **opioid use disorder** were defined as a diagnosis of opioid use disorder within 2 years prior to the index event (IE), medical claims with diagnosis indicating an opioid overdose, or medical claims for nonpharmacological alcohol or drug services. See **Appendix 1** for medical codes (**Table A3 and A4**) and diagnoses (**Table A5**) associated with opioid use disorder treatments.
- **Naloxone treatment** was defined as any paid claims for drugs in the Opioid Reversal Agents preferred drug list (PDL) class or medical claims for naloxone administration (J2310). Pharmacy claims for naloxone would be prescribed in order to prepare for the event of an overdose. Medical claims likely represent naloxone which was actually administered to the patient by a provider in a medical setting, but may also represent some providers who dispense naloxone to patients in the clinic for later use.
- **Duration of MAT** was defined using pharmacy claims. MAT may be billed using a variety of mechanisms (both pharmacy and medical), but only pharmacy claims were used to estimate covered days over the treatment period as days' supply is not available on medical claims. Covered days were estimated based on the days' supply submitted with the pharmacy claim. Oral therapies are administered daily, injectable naltrexone is typically administered every 4 weeks, and buprenorphine implants are administered every 6 months. Duration of treatment was defined as the period of covered days from the first paid claim to the first gap in coverage of at least 14 continuous days. Because the duration of time members were enrolled in FFS was limited, both CCO and FFS claims were used to estimate duration of treatment in the 6 months following the first paid claim. In patients with an initial denied claim, the duration was evaluated in the 6 months following the first paid claim for patients with a subsequent prescription and does not reflect patients without any paid claims.
- **Treatment discontinuation** was defined as a gap in coverage of MAT for 14 or more continuous days. Patients were evaluated for continuation of therapy in the 6 months following the IE.
- The proportion of days covered (PDC) for pharmacy FFS or CCO claims was also used to estimate **adherence to treatment**. The PDC was assessed for the 6 months following the index event. Short-term therapy over a period of 6 months would correspond to a PDC of up to 25% (≤ 45 days), intermediate therapy corresponds to PDC of 25-75% (46 to 135 days), and long-term therapy corresponds to a PDC greater than 75% (>135 days every 6 months). Short-term or intermediate therapy may be indicative of low adherence to treatment or early treatment discontinuation.
- **Return to opioid use** was defined as any paid or denied opioid claims following treatment discontinuation. Duration of opioid use was categorized using the total sum of covered days for paid claims in the 6 months following treatment discontinuation (including both CCO and FFS utilization). In order to

approximate the proportion of patients potentially paying cash for opioid prescriptions, the sum of covered days was also estimated using both paid and denied opioid claims. If there were multiple denied claims for the same prescription, each prescription was only counted once on the date of the earliest claim. Denied claims are only available for FFS patients and were included in estimates of duration if there was not a paid claim for the same prescription number. Error codes associated with included and excluded claims are listed in **Table A7**.

- Patients with **concomitant use of opioids** and MAT were identified based on paid pharmacy claims for MAT and paid claims for a medication within the following PDL classes: opioids, long-acting and opioids, short-acting. Concomitant use was categorized based on the duration of overlapping claims (≤ 30 days or >30 days). To approximate the proportion of patients potentially paying cash for opioid prescriptions, concomitant use was also estimated using both paid and denied opioid claims. If there were multiple denied claims for the same opioid prescription, each prescription was only counted once on the date of the earliest claim.

Results:

Figure 1 shows recent data for utilization of MAT before and after removal of prior authorization criteria for naltrexone and preferred buprenorphine/naloxone products. Utilization of buprenorphine/naloxone and administration of MAT through medical claims has continued to increase while pharmacy claims for naltrexone and buprenorphine-only products remain relatively constant. This is consistent with continued prior authorization requirements for buprenorphine-only products. In recent months there has also been a slight increase in prescribing of naloxone. Increased utilization is likely influenced by community-wide efforts to increase access to naloxone for patients prescribed opioids or MAT, and it is not clear from this data if increased prescribing corresponds to any trend in opioid overdose or poisoning.

Medical claims for MAT which are not impacted by any PA policies follow a similar trend with increasing utilization over time. Medical claims are often billed more frequently than pharmacy claims (with an average claim count of 46-61 claims per person over 6 months) and may include daily administration of buprenorphine/naloxone or methadone. Therefore, the claim count per member per month (as shown on the right axis of the graph) is higher for medical claims compared to pharmacy claims. Approximately, 5-7% of patients evaluated in this analysis have MAT claims billed through both pharmacies and medical clinics, but the focus of this analysis is on pharmacy claims impacted by the change in policy.

Figure 1. Utilization of paid FFS pharmacy claims for medications for OUD (per member per month [PMPM]) from 1/1/2016 to present. Prior authorization was removed for preferred MAT products on March 1, 2017. Utilization of medical claims for OUD is also included for context. Medical claims do not require PA and would not have been impacted by the policy. The count of pharmacy claims is shown on the left axis and the count of medical claims per member per month is measured on the right axis.

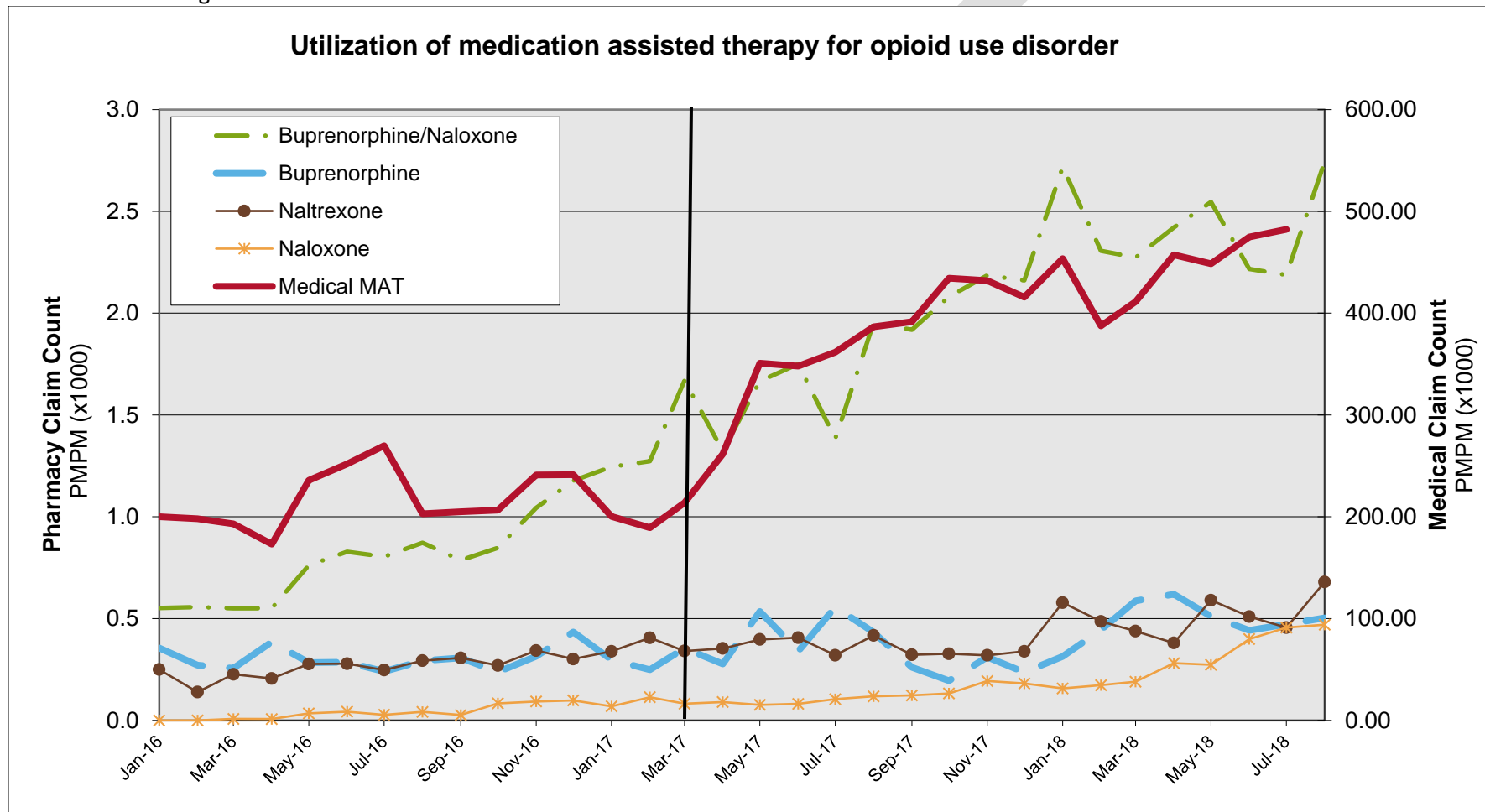


Table 1 lists basic demographics for patients with claims for MAT. Overall, demographics were similar before and after removal of the policy with the majority of claims prescribed to adult patients. Approximately 53-57% were female and 48-51% were white. On average, 17-19% of patients were prescribed doses over 24 mg/day of buprenorphine. Denied claims were slightly higher in patients on high dose buprenorphine (22-28%) compared to patients with an initial paid claim (14-15%). Overall rates were similar before and after removal of the PA criteria.

Table 1. Demographics before and after removal of the policy. Average PDC was evaluated in the 6 months following the index event.

| | Before Group | | After Group | |
|--|------------------|---------|------------------|---------|
| | All Index Events | | All Index Events | |
| | N= 1,045 | | 1,160 | |
| Mean age (range) | 35 | 6-66 | 35 | 9-65 |
| <13 | 2 | 0.2% | 1 | 0.1% |
| 13-18 | 8 | 0.8% | 10 | 0.9% |
| 19-60 | 1,019 | 97.5% | 1,126 | 97.1% |
| >60 | 16 | 1.5% | 23 | 2.0% |
| Female | 596 | 57.0% | 624 | 53.8% |
| White | 529 | 50.6% | 556 | 47.9% |
| Native American | 107 | 10.2% | 158 | 13.6% |
| Buprenorphine dose >= 24 mg/day | 200 | 19.1% | 197 | 17.0% |
| Average days to lost enrollment/CCO enrollment (min/max) | 56 | (0-184) | 53 | (0-184) |

In patients with an initial paid claim, average duration of MAT was 192 days before removal of PA criteria and 151 days after removal of PA criteria (**Table 2**). Duration was defined as the time from the first paid claim to the first gap in coverage of at least 14 days. Over 40% of the population has claims for more than 120 days in the 6 months following the index event, and about 30% of the population had less than 30 days of continuous therapy following their first paid claim. Rates were similar both before and after removal of the PA criteria. If patients had an initial denied MAT claim but a subsequent paid claim, estimates of treatment duration and PDC were similar compared to patients who had an initial paid claim.

Table 2. Duration of treatment and proportion of days covered (PDC) estimates. In patients with an initial denied claim, the duration was evaluated in the 6 months following the first paid claim for patients with a subsequent prescription and does not reflect patients without any paid claims.

| | Before Group | | | | | | After Group | | | | | |
|----------------------------------|------------------|-------|------------------------|-------|--------------------------|-------|------------------|-------|------------------------|-------|--------------------------|-------|
| | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | |
| N= | 1,045 | | 417 | 39.9% | 628 | 60.1% | 1,160 | | 963 | 83.0% | 197 | 17.0% |
| Mean duration of (MAT) treatment | 217 | | 192 | | 224 | | 152 | | 151 | | 154 | |
| 1-7 days | 36 | 3.4% | 10 | 2.4% | 26 | 4.1% | 66 | 5.7% | 60 | 6.2% | 6 | 3.0% |
| 8-30 days | 199 | 19.0% | 127 | 30.5% | 72 | 11.5% | 256 | 22.1% | 231 | 24.0% | 25 | 12.7% |
| 31-60 days | 106 | 10.1% | 52 | 12.5% | 54 | 8.6% | 147 | 12.7% | 133 | 13.8% | 14 | 7.1% |
| 61-120 days | 126 | 12.1% | 62 | 14.9% | 64 | 10.2% | 135 | 11.6% | 118 | 12.3% | 17 | 8.6% |
| >120 days | 465 | 44.5% | 166 | 39.8% | 299 | 47.6% | 513 | 44.2% | 421 | 43.7% | 92 | 46.7% |
| Average PDC in 6 months after IE | | | | | | | | | | | | |
| PDC <= 25% | 297 | 28.4% | 100 | 24.0% | 197 | 31.4% | 320 | 27.6% | 253 | 26.3% | 67 | 34.0% |
| PDC 26%-75% | 273 | 26.1% | 136 | 32.6% | 137 | 21.8% | 283 | 24.4% | 242 | 25.1% | 41 | 20.8% |
| PDC > 75% | 475 | 45.5% | 181 | 43.4% | 294 | 46.8% | 557 | 48.0% | 468 | 48.6% | 89 | 45.2% |

Table 3 shows the number of patients with a paid or denied index event stratified by drug. After removal of prior authorization criteria, 83% of patients had an initial paid claim for MAT compared to 40% of patients in the year before the PA was removed. There was relatively little change in the number of patients with approved or denied claims for non-preferred products, and 93% of patients with denied claims were for buprenorphine-only products after removal of the PA criteria.

Table 3. Patients with pharmacy claims for MAT before and after implementation of the policy.

| | Before Group | | | | | | After Group | | | | | |
|-------------------------------|------------------|-------|------------------------|-------|--------------------------|-------|------------------|-------|------------------------|-------|--------------------------|-------|
| | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | |
| N= | 1,045 | | 417 | 39.9% | 628 | 60.1% | 1,160 | | 963 | 83.0% | 197 | 17.0% |
| Index Event by Drug | | | | | | | | | | | | |
| Naltrexone | 198 | 18.9% | 190 | 45.6% | 8 | 1.3% | 266 | 22.9% | 264 | 27.4% | 2 | 1.0% |
| Buprenorphine/naloxone | 608 | 58.2% | 180 | 43.2% | 428 | 68.2% | 646 | 55.7% | 635 | 65.9% | 11 | 5.6% |
| Buprenorphine only products | 239 | 22.9% | 47 | 11.3% | 192 | 30.6% | 248 | 21.4% | 64 | 6.6% | 184 | 93.4% |
| Naloxone in 6 months after IE | 39 | 3.7% | 16 | 3.8% | 23 | 3.7% | 96 | 8.3% | 87 | 9.0% | 9 | 4.6% |

Diagnoses associated with claims for MAT are described in **Table 4**. Approximately 85% of patients were classified as having an OUD based on available diagnoses or presence of medical claims for OUD. Rate of diagnoses was similar before and after the policy, indicating that there was little change in off-label prescribing patterns despite reduced restrictions for preferred buprenorphine/naloxone products. Rates were similar between patients with paid and denied IE, and a large proportion of patients with a denied IE had a diagnosis of OUD.

Table 4. Diagnoses related to MAT use. Patients may have more than one opioid diagnosis or off-label diagnosis.

| | Before Group | | | | | | After Group | | | | | |
|--|------------------|-------|------------------------|-------|--------------------------|-------|------------------|-------|------------------------|-------|--------------------------|-------|
| | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | |
| N= | 1,045 | | 417 | 39.9% | 628 | 60.1% | 1,160 | | 963 | 83.0% | 197 | 17.0% |
| Total with OUD | 892 | 85.4% | 330 | 79.1% | 562 | 89.5% | 997 | 85.9% | 834 | 86.6% | 163 | 82.7% |
| Diagnosis of opioid use, dependence, or abuse | 829 | 79.3% | 274 | 65.7% | 555 | 88.4% | 909 | 78.4% | 745 | 77.4% | 164 | 83.2% |
| Other diagnoses or medical claims indicating OUD (poisoning or non-pharmacological claims for drug services) | 591 | 56.6% | 245 | 58.8% | 346 | 55.1% | 723 | 62.3% | 626 | 65.0% | 97 | 49.2% |
| Total patients without diagnoses of OUD | 151 | 14.4% | 87 | 20.9% | 64 | 10.2% | 162 | 14.0% | 129 | 13.4% | 33 | 16.8% |
| Other substance use disorders | 73 | 7.0% | 50 | 12.0% | 23 | 3.7% | 61 | 5.3% | 54 | 5.6% | 7 | 3.6% |
| Chronic pain | 30 | 2.9% | 9 | 2.2% | 21 | 3.3% | 37 | 3.2% | 23 | 2.4% | 14 | 7.1% |

The disposition of patients with denied index events for MAT is shown in **Table 5**. Approximately 66-73% of patients had a subsequent paid claim for MAT within 30 days of the denial. In 19-23% of patients, a PA was never requested for the patient. The majority of patients (69-70%) without subsequent paid claims for MAT did have a diagnosis of OUD. OUD was defined based on diagnosis codes for opioid abuse, dependence, and use or based on medical claims indicating OUD (such as diagnoses of opioid poisoning or non-pharmacological claims for drug services).

Table 5. Disposition of denied pharmacy claims before and after removal of the PA criteria. Longer time between the initial denial and a paid claim may indicate barriers to treatment for appropriate use, whereas a large volume of PA denials may indicate use for inappropriate high dose of off-label treatment.

| | Before Group | | After Group | |
|--|--------------|-------|-------------|-------|
| | N | % | N | % |
| Index Event Denied Claim | 628 | | 197 | |
| MAT pharmacy claim filled OR paid medical claim for MAT within 30 days | 459 | 73.1% | 131 | 66.5% |
| MAT pharmacy claim filled OR paid medical claim for MAT within 90 days | 48 | 7.6% | 20 | 10.2% |
| Never had a Medication Assisted Therapy (MAT) claim within 90 days of a denied claim | 121 | 19.3% | 46 | 23.4% |
| PA not requested in the 5 days before or 30 days after the denied claim | 116 | 95.9% | 43 | 93.5% |
| PA denied in the 5 days before or 30 days after the initial denied claim | 0 | 0.0% | 0 | 0.0% |
| Never received drug and had diagnosis of OUD | 83 | 68.6% | 32 | 69.6% |

Table 6 evaluates impact of MAT on long-term outcomes. Overall, incidence of clinical outcomes was similar before and after the policy implementation. Approximately 4% of patients with claims for MAT had a subsequent diagnoses of opioid overdose, acute intoxication, or medical claims for naloxone in the 6 months following the index event. However, it is concerning that a large majority of these patients did not have a paid pharmacy claim for naloxone in that same timeframe. Less than 1% of patients had 2 or more claims for naloxone.

Use of concomitant or subsequent opioid use was also evaluated. Overall use of opioids was limited following an initial claim for MAT. After MAT initiation, 90-93% of patients had less than 7 days of opioid therapy in the following 6 months. Proportions were similar for all patients regardless of whether they had a paid or denied index event for MAT. Approximately 64-67% of patients discontinued MAT treatment in the 6 months following an initial claim. Of patients who discontinued MAT treatment (defined as a continuous gap coverage of at least 14 days), 28% and 19% of patients had a subsequent claim an opioid prescription in the before and after groups, respectively (data not shown). Similarly, few patients had concurrent utilization of MAT and concurrent utilization was generally for short durations. Only 10-13% of patient had concurrent paid claims for opioids and MAT, and duration on concomitant use exceeded 30 days in only 0.7%-2.2% of patients. Upon evaluation of both paid and denied opioid claims, there was very little change in duration of opioid use compared to analysis of only paid opioid claims (data not shown). This indicates that cash paying for opioids may be less of an issue for this population.

Table 6. Impact of MAT on long-term outcomes. Patients may be counted more than once in each category. All outcomes were evaluated in the 6 months following the index event.

| | Before Group | | After Group | |
|---|------------------|-------|------------------|-------|
| | All Index Events | | All Index Events | |
| N= | 1,045 | | 1,160 | |
| Patients with diagnosis of opioid overdose, acute intoxication, or medical claims for naloxone | 40 | 3.8% | 48 | 4.1% |
| Patients categorized above AND without a paid pharmacy claim for naloxone in the 6 months following the event | 40 | 3.8% | 45 | 3.9% |
| Patients with ≥2 paid claims for naloxone | 2 | 0.2% | 9 | 0.8% |
| Duration of opioid use in the following 6 months (paid claims) | | | | |
| ≤7 days | 941 | 90.0% | 1,080 | 93.1% |
| 8-30 days | 63 | 6.0% | 55 | 4.7% |
| 31-60 days | 20 | 1.9% | 10 | 0.9% |
| 61-120 days | 9 | 0.9% | 8 | 0.7% |
| >120 days | 12 | 1.1% | 7 | 0.6% |

Utilization of non-pharmacological services is shown in **Table 7**. With removal of the criteria, patients were no longer required to be enrolled in a treatment program with use of preferred products. However, utilization of counseling and non-pharmacological services was similar before and after removal of the PA

criteria. Overall, 39-40% of patients had at least one claim for non-pharmacological SUD services, and approximately 34% of patients had long-term non-pharmacological therapy after 3 months of treatment with MAT.

Table 7. Utilization of non-pharmacological psychosocial support or enrollment in SUD treatment programs.

| | Before Group | | | | | | After Group | | | | | |
|--|------------------|-------|------------------------|-------|--------------------------|-------|------------------|-------|------------------------|-------|--------------------------|-------|
| | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | | All Index Events | | Index Event Paid Claim | | Index Event Denied Claim | |
| N= | 1,045 | | 417 | 39.9% | 628 | 60.1% | 1,160 | | 963 | 83.0% | 197 | 17.0% |
| Patients with any medical claims for non-pharmacological SUD services (in 6 months after IE) | 405 | 38.8% | 187 | 44.8% | 218 | 34.7% | 467 | 40.3% | 402 | 41.7% | 65 | 33.0% |
| Patients with medical claims for non-pharmacological SUD services for more than 3 months after the IE (From 3 months after IE to 9 months after IE) | 356 | 34.1% | 162 | 38.8% | 194 | 30.9% | 396 | 34.1% | 340 | 35.3% | 56 | 28.4% |

Discussion and limitations:

Several limitations exist as a result of the retrospective nature of this analysis. First, data is based on claims history which may not accurately reflect true patient diagnoses or correlate with actual medication adherence. For example, pharmacy claims for naloxone are typically prescribed as a precautionary measure in order to prepare for the event of an overdose and may not correlate to actual rates of overdose. Medical claims likely represent naloxone which was actually administered to the patient by a provider in a medical setting, but may also represent some providers who dispense naloxone to patients in the clinic for later use. Both medical claims and pharmacy claims may not capture administration of naloxone by friends, family, emergency medical technicians, or first responders. Both ICD-9 and ICD-10 diagnosis codes were used to identify diagnoses for patients. Though efforts were made to accurately identify comparable codes, there may be differences in diagnoses based on the ICD version for claims identified before and after October 2015 when the ICD-10 version was implemented. For example, ICD-10 diagnoses have 3 distinct codes for opioid dependence, abuse, or use whereas ICD-9 codes for OUD describe populations with opioid dependence/abuse and non-dependent opioid abuse.

In addition, use of proportion of days covered attempts to estimate the frequency which a patient takes a prescription, but accuracy of this method has not been validated and patients may not always be categorized appropriately. For example, a patient with PDC less than 25% over 6 months could have up to 45 days of continuous coverage in the reporting period and could be indicative of long-term therapy initiation or only a brief treatment duration. Similarly, treatment discontinuation as defined in this analysis (>14 days gap in coverage) may not accurately capture patients who have brief interruptions in therapy or discontinue but re-initiate therapy. Because many patients transition in and out of CCOs duration of therapy and PDC estimates included paid claims for both FFS and CCOs. However, policies surrounding MAT may be different between CCOs which may impact estimates of therapy duration.

This analysis does not evaluate use of MAT when administered in a clinical setting. MAT may be billed using a variety of mechanisms (both pharmacy and medical), but only pharmacy claims were included in this analysis. Medical claims are often billed with multiple mechanisms, and therefore, the number and

duration of claims is often difficult to quantify. However, based on current estimates, only a small proportion of included patients (5-7%) had both medical and pharmacy claims for MAT.

Similarly, though the analysis included data on paid pharmacy claims from both CCO and FFS, data may still be incomplete. For example, in members with denied claims and no subsequent paid pharmacy claims for MAT, 93% of members did not have a PA request. However, some of these members may have paid medical claims for MAT or transitioned into a CCO for which there may be different policies for MAT. In this population, the average number of days members were enrolled in FFS was 53-56 days, and continuity of care as members transition between FFS and CCOs may affect coverage of medications.

Removal of the PA criteria for preferred MAT products allowed increased access to MAT in the FFS population. However, ongoing national and state-wide efforts may have also enhanced access to or referral for treatment of OUD and may account for the increasing utilization of MAT. For example, factors which may impact utilization of MAT include changes in opioid prescribing patterns, increased awareness and diagnoses of OUD, efforts to increase the number of prescribing providers for buprenorphine, and availability of medical clinics for treatment of OUD. Similarly, recent utilization trends for naloxone for prevention of overdose are likely influenced by increased awareness for risks of overdose, increased prescribing from available providers, and effort to enhance access to naloxone.

References:

1. SAMHSA: Substance Abuse and Mental Health Services Administration. Medication-Assisted Treatment (MAT). 2018; <https://www.samhsa.gov/medication-assisted-treatment>. Accessed October 15, 2018.
2. The Management of Substance Use Disorders Work Group. VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF SUBSTANCE USE DISORDERS. 2015; <https://www.healthquality.va.gov/guidelines/MH/sud/>. Accessed October 15, 2018.

Appendix 1: Coding for methods and definitions

Table A1. Pharmacy codes for MAT

| GSN | Route | FormDesc | Generic | PDL |
|--------|-------|----------|--------------------------------|-----|
| 066635 | SL | FILM | buprenorphine HCl/naloxone HCl | Y |
| 066636 | SL | FILM | buprenorphine HCl/naloxone HCl | Y |
| 070259 | SL | FILM | buprenorphine HCl/naloxone HCl | Y |
| 070262 | SL | FILM | buprenorphine HCl/naloxone HCl | Y |
| 051640 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 051641 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 071189 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 071190 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 073424 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 073425 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 074685 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 076981 | SL | TAB SUBL | buprenorphine HCl/naloxone HCl | Y |
| 004518 | PO | TABLET | naltrexone HCl | Y |

| | | | | |
|--------|----|------------|--------------------------------|---|
| 060935 | IM | SUS ER REC | naltrexone microspheres | Y |
| 077999 | SQ | SOLER SYR | buprenorphine | N |
| 078000 | SQ | SOLER SYR | buprenorphine | N |
| 029312 | SL | TAB SUBL | buprenorphine HCl | N |
| 029313 | SL | TAB SUBL | buprenorphine HCl | N |
| 072449 | BC | FILM | buprenorphine HCl/naloxone HCl | N |
| 072450 | BC | FILM | buprenorphine HCl/naloxone HCl | N |
| 072451 | BC | FILM | buprenorphine HCl/naloxone HCl | N |
| 076145 | IL | IMPLANT | buprenorphine HCl | |

Table A2. Error Codes for denied OUD claims

Included Codes

| Error Code | Description |
|-------------------|---|
| 4026 | DAY SUPPLY LIMIT EXCEEDED FOR COVERED NDC |
| 2603 | Recipient Locked in |
| 4167 | DRUG QUANTITY PER DAY LIMIT EXCEEDED |
| 3000 | UNITS EXCEED AUTHORIZED UNITS ON PA MASTER FILE |
| 3002 | NDC REQUIRES PA |

Excluded Codes

| Error Code | Description |
|-------------------|---|
| 1017 | NON-REBATABLE ELIGIBLE INDICATOR |
| 505 | THIRD PARTY PAYMENT AMOUNT MORE THAN CLAIM CHARGE |
| 3343 | Questionable TPL amount |
| 628 | Other Coverage Reject Code Required for OCC 3 |
| 2507 | RECIPIENT HAS MORE THAN ONE INSURANCE CARRIER |
| 4007 | NON-COVERED NDC DUE TO CMS TERMINATION |
| 4890 | Non covered drug class |
| 4891 | Not covered drug class |
| 643 | INVALID OTHER COVERAGE CODE |
| 238 | RECIPIENT NAME IS MISSING |
| 2809 | DOB IS INVALID |
| 5001 | EXACT DUPLICATE |
| 513 | RECIPIENT NAME AND NUMBER DISAGREE |
| 4999 | THIS DRUG IS COVERED BY MEDICARE PART D |
| 4002 | Non-Covered Drug |
| 576 | CLAIM HAS THIRD-PARTY PAYMENT |
| 2002 | RECIPIENT NOT ELIGIBLE FOR HEADER DATE OF SERVICE |

| | |
|------|--|
| 2017 | RECIPIENT SERVICES COVERED BY HMO PLAN |
|------|--|

Table A3. Medical Codes for MAT

| HCPCS | Description |
|--------------|--|
| H0020 | Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed practitioner) |
| J3490, J3590 | Include only if associated with any of the pharmacy drug codes for MAT (see Table A1) or with methadone (GSNs 004237 004238; 004239; 004240; 004242; 023767) |
| J0571 | Buprenorphine oral 1mg |
| J0570 | Buprenorphine implant 74.2mg (Probuphine) |
| Q9991 | Buprenorphine XR less than or equal to 100mg (Sublocade) |
| Q9992 | Buprenorphine XR over 100mg (Sublocade) |
| J0592 | Buprenorphine hydrochloride |
| J0572 | Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine |
| J0573 | Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine |
| J0574 | Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine |
| J0575 | Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine |
| J2310 | Injection, naloxone hydrochloride, per 1 mg |
| J2315 | Injection, naltrexone, depot form, 1 mg (Vivitrol) |

Table A4. Medical codes for non-pharmacological drug abuse services

| HCPCS | Description |
|-------|---|
| H0005 | Alcohol and/or drug services; group counseling by a clinician |
| H0006 | Alcohol and/or drug services; case management |
| H0007 | Alcohol and/or drug services; crisis intervention (outpatient) |
| H0008 | Alcohol and/or drug services; sub-acute detoxification (hospital inpatient) |
| H0009 | Alcohol and/or drug services; acute detoxification (hospital inpatient) |
| H0010 | Alcohol and/or drug services; sub-acute detoxification (residential addiction program inpatient) |
| H0011 | Alcohol and/or drug services; acute detoxification (residential addiction program inpatient) |
| H0012 | Alcohol and/or drug services; sub-acute detoxification (residential addiction program outpatient) |
| H0013 | Alcohol and/or drug services; acute detoxification (residential addiction program outpatient) |
| H0014 | Alcohol and/or drug services; ambulatory detoxification |
| H0015 | Alcohol and/or drug services; intensive outpatient (treatment program that operates at least 3 hours) |
| H0016 | Alcohol and/or drug services; medical/somatic (medical intervention in ambulatory setting) |
| H0050 | Alcohol and/or drug services, brief intervention, per 15 minutes |
| S9475 | Ambulatory setting substance abuse treatment or detoxification services, per diem |

| | |
|-------|---|
| T1006 | Alcohol and/or substance abuse services, family/couple counseling |
| T1007 | Alcohol and/or substance abuse services, treatment plan development and/or modification |
| T1012 | Alcohol and/or substance abuse services, skills development |
| H2034 | Alcohol and/or drug abuse halfway house services, per diem |
| H0047 | Alcohol and/or other drug abuse services, not otherwise specified |
| OR312 | Alcohol and/or substance abuse services |
| H0029 | Alcohol and/or drug prevention alternatives service (services for populations that exclude alcohol a |
| H0028 | Alcohol and/or drug prevention problem identification and referral service (e.g., student assistance |
| H0026 | Alcohol and/or drug prevention process service, community-based (delivery of services to develop ski |
| H0022 | Alcohol and/or drug intervention service (planned facilitation) |
| H2035 | Alcohol and/or other drug treatment program, per hour |
| H2036 | Alcohol and/or other drug treatment program, per diem |
| 4306F | Patient counseled regarding psychosocial and pharmacologic treatment options for opioid addiction (sud) |

Table A5. Diagnosis codes for opioid use disorder and opioid overdose

| Code | Description | ICD Version Code |
|-----------------|---|------------------|
| F111x | Opioid abuse | 10 |
| F112x | Opioid dependence | 10 |
| F119x | Opioid use | 10 |
| 3040x | Addiction or dependence heroin, opioids, opium | 9 |
| 3047x | Combinations of opioid type drug with any other drug dependence | 9 |
| 3055x | Nondependent opioid abuse | 9 |
| F1112x | Opioid abuse with intoxication | 10 |
| F1122x | Opioid dependence with intoxication | 10 |
| F1192x | Opioid use, unspecified with intoxication | 10 |
| T400xxx-T400X5x | Poisoning by, adverse effect of opium | 10 |
| T401xxx-T401X5x | Poisoning by, adverse effect of heroin | 10 |
| T402xxx-T402X5x | Poisoning by, adverse effect of other opioids | 10 |
| T403xxx-T403X5x | Poisoning by, adverse effect of methadone | 10 |
| T404xxx-T404X5x | Poisoning by, adverse effect of other synthetic narcotics | 10 |
| T4060xx-T40605x | Poisoning by, adverse effect of other and unspecified narcotics | 10 |
| T4069xx-T40695x | Poisoning by, adverse effect of other narcotics | 10 |
| 9650x | Poisoning by opiates and related narcotics | 9 |
| E9350-E9352 | Analgesics antipyretics and antirheumatics causing adverse effects in therapeutic use | 9 |

| | | |
|-------|---|---|
| E9802 | Poisoning by other sedatives and hypnotics, undetermined whether accidentally or purposely inflicted | 9 |
| E9800 | Poisoning by analgesics, antipyretics, and antirheumatics, undetermined whether accidentally or purposely inflicted | 9 |

Table A6. Other Relevant diagnoses

Chronic pain diagnoses

| CodeDiagCondMedl | TextDesc | ICD_Version_Code | Category |
|------------------|--|------------------|-------------------------------|
| 3078 | Pain disorders related to psychological factors | 9 | Chronic Pain |
| 30780 | Psychogenic pain, site unspecified | 9 | Chronic Pain |
| 30789 | Other pain disorders related to psychological factors | 9 | Chronic Pain |
| 338 | Pain not elsewhere classified | 9 | Chronic Pain |
| 3380 | Central pain syndrome | 9 | Chronic Pain |
| 3382 | Chronic pain | 9 | Chronic Pain |
| 33821 | Chronic pain due to trauma | 9 | Chronic Pain |
| 33822 | Chronic post-thoracotomy pain | 9 | Chronic Pain |
| 33828 | Other chronic postoperative pain | 9 | Chronic Pain |
| 33829 | Other chronic pain | 9 | Chronic Pain |
| 3383 | Neoplasm related pain (acute) (chronic) | 9 | Chronic Pain |
| 3384 | Chronic pain syndrome | 9 | Chronic Pain |
| F454 | Pain disorders related to psychological factors | 10 | Chronic Pain |
| F4541 | Pain disorder exclusively related to psychological factors | 10 | Chronic Pain |
| F4542 | Pain disorder with related psychological factors | 10 | Chronic Pain |
| G89 | Pain, not elsewhere classified | 10 | Chronic Pain |
| G890 | Central pain syndrome | 10 | Chronic Pain |
| G892 | Chronic pain, not elsewhere classified | 10 | Chronic Pain |
| G8921 | Chronic pain due to trauma | 10 | Chronic Pain |
| G8922 | Chronic post-thoracotomy pain | 10 | Chronic Pain |
| G8928 | Other chronic postprocedural pain | 10 | Chronic Pain |
| G8929 | Other chronic pain | 10 | Chronic Pain |
| G893 | Neoplasm related pain (acute) (chronic) | 10 | Chronic Pain |
| G894 | Chronic pain syndrome | 10 | Chronic Pain |
| F10x | Alcohol related disorders | 10 | Other Substance Use Disorders |

| | | | |
|-------------|---|----|-------------------------------|
| F12x | Cannabis related disorders | 10 | Other Substance Use Disorders |
| F13x | Sedative, hypnotic, or anxiolytic related disorders | 10 | Other Substance Use Disorders |
| F14x | Cocaine related disorders | 10 | Other Substance Use Disorders |
| F15x | Other stimulant related disorders | 10 | Other Substance Use Disorders |
| F16x | Hallucinogen related disorders | 10 | Other Substance Use Disorders |
| F19x | Other psychoactive substance related disorders | 10 | Other Substance Use Disorders |
| 3050x-3054x | Nondependent drug abuse of various types | 9 | Other Substance Use Disorders |
| 3056x-3059x | Nondependent drug abuse of various types | 9 | Other Substance Use Disorders |
| 3041x-3046x | Drug dependence of various types (excluding opioid) | 9 | Other Substance Use Disorders |
| 3048x-3049x | Drug dependence of various types (excluding opioid) | 9 | Other Substance Use Disorders |
| 303x | Alcohol dependence syndrome | 9 | Other Substance Use Disorders |

Table A7. Error Codes for denied opioid claims

Included Codes

| Error Code | Description |
|-------------------|---|
| 2603 | Recipient Locked in |
| 7001 | INFORMATIONAL PRODUR ALERT |
| 628 | Other Coverage Reject Code Required for OCC 3 |
| 505 | THIRD PARTY PAYMENT AMOUNT MORE THAN CLAIM CHARGE |
| 1040 | PRESCRIBING PHYSICIAN NOT ENROLLED |
| 3000 | UNITS EXCEED AUTHORIZED UNITS ON PA MASTER FILE |
| 4025 | AGE IS NOT ALLOWED FOR NDC |
| 6845 | Narcotic Analgesics Duplication |
| 1000 | BILLING PROVIDER ID NOT ON FILE |
| 643 | INVALID OTHER COVERAGE CODE |
| 3002 | NDC REQUIRES PA |
| 7002 | CLAIM DENIED FOR PRODUR REASONS |
| 4167 | DRUG QUANTITY PER DAY LIMIT EXCEEDED |
| 3022 | Non-Pref Drug. Prior Authorization Required. |
| 1026 | PRESCRIBING PHYSICIAN ID NOT ON FILE |
| 7000 | CLAIM FAILED A PRODUR ALERT |
| 6899 | SHORT-ACTING OPIOID MAX 7-DAY SUPPLY EXCEEDED |
| 4175 | OPIATES DRUG QUANTITY PER DAY LIMIT EXCEEDED |
| 2508 | RECIPIENT COVERED BY PRIVATE INSURANCE (PHARMACY) |
| 4165 | DRUG QUANTITY PER DAY LIMIT EXCEEDED |
| 4999 | THIS DRUG IS COVERED BY MEDICARE PART D |

| | |
|------|--|
| 576 | CLAIM HAS THIRD-PARTY PAYMENT |
| 2017 | RECIPIENT SERVICES COVERED BY HMO PLAN |

Excluded Codes

| Error Code | Description |
|-------------------|---|
| 2808 | DOB IS MISSING |
| 219 | QUANTITY DISPENSED IS MISSING |
| 268 | BILLED AMOUNT MISSING |
| 222 | DAYS SUPPLY INVALID |
| 2804 | CASE NUMBER NOT ON FILE |
| 911 | INTERNAL ERROR |
| 221 | DAYS SUPPLY MISSING |
| 1017 | NON-REBATABLE ELIGIBLE INDICATOR |
| 502 | DATE DISPENSED EARLIER THAN DATE PRESCRIBED |
| 1016 | NON-PARTICIPATING MANUFACTURER |
| 4007 | NON-COVERED NDC DUE TO CMS TERMINATION |
| 4127 | CANNOT PRIORITIZE RECIPIENT'S PROGRAMS |
| 4026 | DAY SUPPLY LIMIT EXCEEDED FOR COVERED NDC |
| 351 | REFILL NOT ALLOWED FOR NARCOTIC DRUGS |
| 5000 | POSSIBLE DUPLICATE |
| 238 | RECIPIENT NAME IS MISSING |
| 2807 | MATCH CODE INVALID |
| 3343 | Questionable TPL amount |
| 2809 | DOB IS INVALID |
| 5001 | EXACT DUPLICATE |
| 513 | RECIPIENT NAME AND NUMBER DISAGREE |
| 4891 | Not covered drug class |
| 4890 | Non covered drug class |
| 4002 | Non-Covered Drug |
| 2002 | RECIPIENT NOT ELIGIBLE FOR HEADER DATE OF SERVICE |