Colorado
Medicaid Fee-For-Service (FFS)
Federal Fiscal Year (FFY) 2020
Drug Utilization Review (DUR)
Annual Report

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Section I – Number of Beneficiaries

Question	Response
1. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in your state's Medicaid Fee-For-Service (FFS) program that have a pharmacy benefit?	**1,149,623**
2. On a monthly average, how many of your state's Medicaid beneficiaries are enrolled in managed care plan(s)?	**128,888**

Section II - Prospective DUR (ProDUR)

Question	Response
1. Indicate the type of your pharmacy point of service (POS) vendor.	**Contractor**
a. Vendor Name	**Magellan Health, Inc.**
b. Who processes the state's National Council for Prescription Drug Programs (NCPDP) transactions?	**POS vendor is a separate Pharmacy Benefits Manager (PBM)**
2. Identify your ProDUR table driven criteria source. This would be initial ratings such as drug to drug interactions, dose limits based on age and pregnancy severity.	**First Databank**
Other, please specify.	N/A
3. When the pharmacist receives a ProDUR alert message that requires a pharmacist's review, does your system allow the pharmacist to override the alert using the "NCPDP drug use evaluation codes" (reason for service, professional service and resolution)?	**Varies by Alert Type**
If "Yes" or "Varies by Alert Type,"	Alerts can be overridden with standard professional codes, Other
Other, please explain.	Selected ProDUR alerts may be overridden by pharmacists with standard professional codes.
4. Does your state receive periodic reports providing individual pharmacy providers DUR alert override activity in summary and/or in detail?	**Yes**
a. How often does your state receive reports?	**Ad hoc (on request)**
Other, please explain.	N/A
b. If you receive reports, does your state follow up with those providers who routinely override with interventions?	**Yes**
Yes, what method does your state follow up?	Refer to Program Integrity for Review
Other, please explain.	N/A
No, please explain.	N/A
5. Early Refill	
a. At what percent threshold do you set your system to edit?	
i) Non-controlled drugs:	**75%**
ii) Schedule II controlled drugs:	**85%**
iii) Schedule III through V controlled drugs:	**85%**

Question	Response
b. For non-controlled drugs: when an early refill message occurs, does your state require a PA?	**Yes**
If "Yes" or "Dependent on medication or situation," who obtains authorization?	Pharmacist or Prescriber
If "No," can the pharmacist override at the POS?	N/A
c. For controlled drugs: when an early refill message occurs, does your state require a PA?	**Yes**
If "Yes," who obtains authorization?	Pharmacist or Prescriber
If "No," can the pharmacist override at the POS?	N/A
6. When the pharmacist receives an early refill DUR alert message that requires the pharmacist's review, does your state's policy allow the pharmacist to override for situations such as:	
a. Lost/stolen Rx	**No**
b. Vacation	**No**
c. Other, please explain.	**Pharmacist overrides at the POS are not allowed for lost/stolen Rx's or vacation requests. However, pharmacists may contact the pharmacy call center help desk to request authorization to override these edits.**
7. Does your system have an accumulation edit to prevent patients from continuously filling prescriptions early?	**Yes**
If "Yes," please explain your edit.	A cumulative total of 20 days is allowed over a 180-day period for non-mail order transactions.
If "No," does your state plan to implement this edit?	N/A
8. Does the state Medicaid program have any policy prohibiting the auto-refill process that occurs at the POS (i.e. must obtain beneficiary's consent prior to enrolling in the auto-refill program)?	**No**
9. For drugs not on your Preferred Drug List (PDL), does your Medicaid program have a documented process (i.e. PA) in place, so that the Medicaid beneficiary or the Medicaid beneficiary's prescriber may access any covered outpatient drug when medically necessary?	**Yes**
Yes, please.	Automatic PA based on diagnosis codes or systematic review, Trial and failure of first or second line therapies, Pharmacist or technician reviews, Other

Question	Response
Other, please explain.	Prescribers may submit a pharmacy prior authorization request to the State's PBM, 24 hours a day/7 days a week, by phone or fax. Prior authorization denials are eligible for expanded clinical review after the prescriber submits additional patient-specific documentation and/or clinical literature to support medical necessity. If the expanded review also results in a denial, a formal appeals process is available for both prescribers and members.
No, please explain.	N/A
a. Does your program provide for the dispensing of at least a 72-hour supply of a COD in an emergency situation?	**Yes**
Yes, please.	Other process
Other process, please explain.	Pharmacists or prescribers may call the Magellan pharmacy help desk t request an emergency override to dispense a 3-day supply of a medication in an emergency situation.
No, please explain.	N/A
10. Please list the requested data in each category in Table 1 - Top Drug Claims Data Reviewed by the DUR Board below.	

Table 1 – Top Drug Claims Data Reviewed by the DUR Board

Top 10 Prior Authorization (PA) Requests by Drug Name, report at generic ingredient level	Top 10 Prior Authorization (PA) Requests by Drug Class	Top 5 Claim Denial Reasons (i.e. Quantity Limits (QL), Early Refill (ER), PA, Therapeutic Duplications (TD) and Age Edits (AE))	Top 10 Drug Names by Amount Paid, report at generic ingredient level	% of Total Spent for Drugs by Amount Paid (From data in Column 4, Determine the % of total drug spend)	Top 10 Drug Names by Claim Count, report at generic ingredient level	Drugs by Claim Count % of Total Claims (From data in Column 6, Determine the % of total claims)
buprenorphine/ naloxone	opioids	prior authorization required	adalimumab	5.84%	albuterol sulfate	3.58%
dextroamphetamine /amphetamine	miscellaneous	early refill: overuse precaution	insulin aspart	2.62%	gabapentin	2.35%
methylphenidate	other dermatologic agents	plan limitations exceeded	elexacaftor/ tezacaftor/ ivacaftor	2.38%	fluticasone propionate	1.88%
oxycodone	amphetamine	drug-drug interaction	bictegravir/ emtricitabine/ tenofovir	2.28%	levothyroxine sodium	1.72%
clindamycin	antidepressants	product/ service not covered - plan/benefit exclusion	lurasidone	2.00%	amoxicillin	1.61%
tretinoin	diabetes agents		fluticasone/ salmeterol	1.95%	sertraline	1.57%
galcanezumab	tranquilizers		albuterol sulfate	1.87%	ibuprofen	1.57%
lisdexamfetamine	other antibiotics		insulin detemir	1.84%	lisinopril	1.49%
clindamycin/ benzoyl peroxide	non-opioid analgesics		somatropin	1.79%	cetirizine	1.47%
tramadol	CNS stimulants		etanercept	1.72%	hydrocodone/ acetaminophen	1.46%

Question	Response
11. Section 1927(g) (A) of the Social Security Act (the Act) requires that the pharmacist offer patient counseling at the time of dispensing. Who in your state has responsibility for monitoring compliance with the oral counseling requirement?	**Medicaid Program**
Other, please explain.	N/A

Section III – Retrospective DUR (RetroDUR)

Question	Response
1. Indicate the type of vendor that performed your RetroDUR activities during the time period covered by this report.	**Academic Institution**
a. Identify, by name, your RetroDUR vendor.	**The Regents of the University of Colorado School of Pharmacy**
b. Is the RetroDUR vendor the Medicaid Management Information System (MMIS) fiscal agent?	**No**
c. Is the RetroDUR vendor the developer/supplier of your retrospective DUR criteria?	**Yes**
Please explain "Yes" or "No" response.	Initial draft criteria are developed each quarter by faculty at the University of Colorado Skaggs School of Pharmacy (the vendor) then finalized in collaboration with the State's clinical pharmacist team prior to DUR Board review.
d. Does your state customize your RetroDUR vender criteria?	**Yes**
2. How often does your state perform retrospective practitioner-based education?	**Quarterly**
Other, please specify.	N/A
a. How often does your state perform retrospective reviews that involve communication of client specific information to healthcare practitioners (through messaging, fax, or mail)?	**Quarterly**
Other, please specify.	N/A
b. What is the preferred mode of communication when performing RetroDUR initiatives?	**Mailed letters, Newsletters or other non-direct provider communications**
Other, please specify.	N/A
3. Summary 1 – RetroDUR Educational Outreach Summary Summary 1: RetroDUR Educational Outreach is a year-end summary report on retrospective screening and educational interventions. This year-end summary should be limited to the most prominent problems with the largest number of exceptions.	**Interventional letters that contain patient-specific information are prepared and mailed on a quarterly basis. These letters tend to include rotating clinical topics such as high risk opioid prescribing, high risk benzodiazepine prescribing and high risk psychotropic prescribing in children. During FFY 2020 over 3,000 interventional and educational letters were mailed to Colorado Medicaid prescribers.**

	Q1 (Oct 1 to Dec 31, 2019) TOTAL 599 **165 Opioid comparative letters** **95 Children receiving 2 or more antipsychotics for greater than 45 days of the measurement quarter** **339 Opioid plus BZD plus muscle relaxant** **Q2 (Jan 1 to Mar 31, 2020) TOTAL 967** **165 Opioid comparative letters** **95 Children receiving 2 or more antipsychotics for greater than 45 days of the measurement quarter** **339 Opioid plus BZD plus muscle relaxant** **309 Receiving 2 or more BZDs for 90 out of 180 days using most recent data** **59 Immune Globulin informational letters** **Q3 (Mar 31 to Jun 30, 2020) TOTAL 818** **120 Opioid comparative letters** **88 Children receiving 2 or more antipsychotics for greater than 45 days of the measurement quarter** **358 Opioid plus BZD plus muscle relaxant** **252 Receiving 2 or more BZDs for 90 out of 180 days using most recent data** **Q4 (Jul 1 to Sep 30, 2020) TOTAL 642** **83 Children receiving 2 or more antipsychotics for greater than 45 days of the measurement quarter** **328 Opioid plus BZD plus muscle relaxant** **231 Receiving 2 or more BZDs for 90 out of 180 days using most recent data**

Section IV - DUR Board Activity

Question	Response
1. Summary 2 – DUR Board Activities Summary. Summary 2: DUR Board Activities Summary should be a brief descriptive on DUR activities during the fiscal year reported.	**Four DUR Board meetings were held in FFY 2020:** **November 12, 2019 (in person)** **February 11, 2020 (in person)** **May 12, 2020 (virtual)** **August 11, 2020 (virtual)** **Summary of DUR Board meeting discussion and motions made in regard to reviewed ProDUR criteria additions/deletions:** **November 12, 2019:** **Anti-emetics: Discussion regarding chemotherapy-induced nausea and vomiting, as well as duration of approval for agents indicated for nausea and vomiting associated with pregnancy.** **Hepatitis C Virus Treatments (Direct Acting Antivirals): Motion made regarding requirement of SVR 24 occurred for State to investigate further.** **Pulmonary Arterial Hypertension (PAH) Agents (Endothelial Antagonists): Motion made regarding addition of REMS language to criteria.** **Targeted Immune Modulators: Motion made regarding addition of contraindication to definition of failure and trial of TNF inhibitors for receipt of non-preferred agents.** **February 11, 2020:** **Antimigraine Agents (Calcitonin Gene-Related Peptide (CGRP) Inhibitors): Motion made to accept proposed criteria changes with clarification for Emgality dosing by indication and medication overuse headache literature review.** **Multiple Sclerosis Agents: Motion made to accept criteria proposals with added language to protect patients of childbearing age and teratogenesis.** **Immune Globulins: Motion made to accept criteria with addition of LTC or home health clause.** **Atypical Antipsychotics: Motion made for State to reevaluate criteria for Abilify MyCite. Motion was made to accept changes and adjust aripiprazole quantity limits for pediatric patients if incremental dosing is not**

Question	Response
	achievable by currently set limits. **Growth Hormones: Motion was made to add qualifying diagnoses of symptomatic neonatal growth hormone deficiency and small gestational age.** **May 12, 2019:** **Non-Opioid Analgesics: Motion made to accept proposed criteria changes with consideration for expanding access to Tresiba for children.** **Opioids (Short-Acting): Discussion occurred regarding the age requirement for tramadol with consideration that the drug is highly utilized, particularly in children with complex medical conditions. Additionally, recommendation was made to add under the supervision of a pediatric specialist.** **Androgenic Agents: Motion made regarding feedback provided from pediatricians at Children's Hospital that there is no need for breast exam and PSA when used in children, and to recommend adding onset of primary hypogonadism prior to this age 12 years of age and older to the criteria.** **Respiratory Inhalants: Discussion occurred regarding the number of Proair inhalers per month being high. Motion made that quantity limits should change to 2 inhalers per 30 days.** **Nayzilam: Discussion regarding the need for these products and consideration for access occurred. Motion made to remove the need for trial and failure of midazolam vial.** **Valtoco: Motion made to change the criteria to reflect that of Nayzilam.** **August 11, 2020:** **Anticonvulsants (oral): State DUR Pharmacist introduced the discussion for this class and highlighted changes made to this class as the result of previous reviews, including addressing clinical needs, improving access, and providing a fairly extensive preferred agent list. In addition, clarifying DAW1 designations for brand versions of preferred agents in this class for preferred agents do not require PA. Board requested clarification on minimum ages in criteria table for Depakote, Depakene and generic divalproex**

Question	Response
	and valproic acid products, such as the greater than/equal to 10 years age limit being applicable to all valproic acid-containing products. Motion made to change Epidiolex (cannabidiol) criteria so that all bullet points, for consistency, include the phrase diagnosis of seizures associated with for Lennox Gastaut and Dravet syndromes in order to match FDA-approved language. Motion made to create a separate, specific section of criteria for Fintepla (fenfluramine) to be consistent with other anticonvulsants indicated for the management of seizures associated with Dravet syndrome for two bullet points: 1. Member age greater than 2 years and 2. Fintepla being used for the treatment of seizures associated with Dravet syndrome. Discussion occurred regarding value in consultations with providers at National Jewish Health and UCHealth when making therapeutic decisions involving agents in this drug class, explaining that consultation process creates a system of checks and balances between primary care providers and specialists. The Board asked for clarification about new information released from a Phase IV trial with Aptiom (eslicarbazepine) that was mentioned during speaker testimony from Sunovion. Clarification was provided that this trial has not yet been peer reviewed or published at this time leading to Board discussion for not considering any changes to criteria at this time. Motion made to change language in criteria for non-preferred, newly started anticonvulsants to be prescribed by or in consultation with a neurologist. **Stimulants and other ADHD Agents: Motion made to create PA criteria to allow for the use of methylphenidate IR for 4 and 5 year old members whose ADHD symptoms are not controlled despite adequate behavior interventions, based on the American Academy of Pediatrics ADHD Practice Guideline published in October 2019. Discussion occurred regarding possibly making changes in the criteria for Journay PM with consensus to wait until more data**

Question	Response
	becomes available for that product. **Diabetes Management Classes (GLP1 Analogues): Discussion regarding GLP1 medication availability to members who are not able to use an injectable dosage form; since many GLP1 analogues are delivered via a pen, important to consider physical inability to use a pen delivery system (such as lack of manual dexterity) as a treatment failure. Motion made to add inability to self-administer due to dexterity limitations to the list that defines failures.** **Diabetes Management Classes (SGLT2 Inhibitors): Discussion occurred regarding new evidence regarding the benefits of SGLT2 inhibitors (dapagliflozin and empagliflozin) in heart failure, with or without concomitant diabetes; concluding that based on this evidence, the requirement for a 3 month trial of metformin may be considered for removal.** **Anticoagulants: Motion was made to add VTE prophylaxis in the setting of malignancy to criteria for Eliquis (apixiban).** **Colony Stimulating Factors: Motion was made to modify criteria for Udenyca to include lack of caregiver or support system or inadequate access to healthcare facility or home care interventions as bypass criteria for use of the long-acting agent.** **Bone Resorption Suppression and Related Agents: Motion was made to change no history of vertebral fracture to no history of low trauma or fragility fracture in section describing bisphosphonate use after 5 years of therapy.** **Board policies that establish whether and how results of RetroDUR screening are used to adjust ProDUR screens:** **The DUR Board reviews trends in the RDUR reports on a quarterly basis. This process has, in some cases, led to further analyses being conducted by the CO-DUR team, with subsequent recommendations provided to the Colorado Department of Health Care Policy and Financing (HCPF). Inversely, ProDUR criteria can influence RDUR activity when there are utilization trends for a**

Question	Response
	specific drug product or within a specific therapeutic class. This drug use activity may lead to further investigation of the impact of ProDUR changes on prescribing patterns (such as for opioids, benzodiazepines, or psychotropic medications in pediatric members). **DUR Board involvement in the DUR education program (i.e. newsletters, continuing education, etc.):** **RetroDUR prescriber educational outreach letters are reviewed by the DUR Board for input and recommendations. No DUR Newsletters were published during FFY 2020, as funds originally designated to produce two annual DUR Newsletter publications were reallocated to manage a significant increase in contractual expenses required for provision of pain management telephone consultation services.** **Policies adopted to determine mix of patient or provider specific intervention types (i.e. letters, face-to-face visits, increased monitoring):** **Interventional letters that contain patient-specific information are sent to prescribers on a quarterly basis. There is no specific policy to determine the areas of focus for these interventions, although clinical topics are often identified through utilization patterns, changes in FDA product labeling, and clinical module analyses (see Colorado Summary 5: Innovative Practices). The letters tend to include rotating clinical topics such as high risk opioid prescribing, high risk benzodiazepine prescribing and high risk psychotropic prescribing in children.**
2. Does your state have an approved Medication Therapy Management (MTM) Program?	**No**

Section V – Physician Administered Drugs (PAD)

The Deficit Reduction Act required collection of national drug code (NDC) numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for:

Question	Response
1. ProDUR?	**No**
If "No," does your state have a plan to include this information in your DUR criteria in the future?	Yes
2. RetroDUR?	**No**
If "No," does your state have a plan to include this information in your DUR criteria in the future?	Yes

Section VI – Generic Policy and Utilization Data

Question	Response
1. Summary 3 – Generic Drug Substitution Policies Summary 3: Generic Drug Substitution Policies should summarize factors that could affect your generic utilization percentage. In describing these factors, please explain any formulary management or cost containment measures, PDL policies, educational initiatives, technology or promotional factors, or other state specific factors that affects your generic utilization rate.	**Policy for mandated use of generic product formulations (generic mandate):** **Brand name drug products that have generic equivalent product formulations (multi-source innovator products) require a prior authorization. Exceptions to this policy include:** **The brand name drug has been exempted based on indicated use for the following circumstances:** **The Department designates favored coverage of the brand drug product based on net cost for the brand product being lower than that of the generic equivalent** **The physician is of the opinion that a transition to the generic equivalent of a brand drug product would be unacceptably disruptive to the patient's stabilized drug regimen** **The patient is started on a generic drug but is unable to continue treatment on the generic drug as determined by the patient's physician** **Medications used for the treatment of the following disease states are exempt from the generic mandate policy (no PA is required).** **Biologically Based Mental Illness (as defined in 10-16-104 (5.5) C.R.S.)** **Cancer** **Epilepsy** **HIV AIDS** **Other drug management strategies to encourage use of generic product formulations:** **Our program has implemented a Preferred Drug List (PDL) which, by incorporating available evidence-based research and public testimony, provides clinical guidance for necessary drug therapies. During implementation of these clinical recommendations, the program provides advantage to products that are most cost effective. We have been able to enhance generic utilization in a clinically appropriate way without sacrificing quality of care by**

Question	Response
	preferring generic drug options when clinically appropriate.
2. In addition to the requirement that the prescriber write in his own handwriting "Brand Medically Necessary" for a brand name drug to be dispensed in lieu of the generic equivalent, does your state have a more restrictive requirement?	**Yes**
If "Yes,"	Other
Other, please explain.	Prescriptions for multisource innovator medications may require prior authorization with prescriber attestation that (1) transition to the generic equivalent of the brand name product would be unacceptably disruptive to the member's stabilized drug regimen, or (2) that the member is unable to continue treatment with the generic, as determined by the prescriber, following initial treatment.

Generic Drug Utilization Data

Computation Instructions KEY

Single Source (S) – Drugs having an FDA New Drug Application (NDA), and there are no generic alternatives available on the market.

Non-Innovator Multiple-Source (N) – Drugs that have an FDA Abbreviated New Drug Application (ANDA), and generic alternatives exist on the market

Innovator Multiple-Source (I) – Drugs which have an NDA and no longer have patent exclusivity.

1. **Generic Utilization Percentage:** To determine the generic utilization percentage of all covered outpatient drugs paid during this reporting period, use the following formula:

$$N \div (S + N + I) \times 100 = \text{Generic Utilization Percentage}$$

2. **Generic Expenditures:** To determine the generic expenditure percentage (rounded to the nearest $1000) for all covered outpatient drugs for this reporting period use the following formula:

$$\$N \div (\$S + \$N + \$I) \times 100 = \text{Generic Expenditure Percentage}$$

CMS has developed an extract file from the Medicaid Drug Rebate Program Drug Product Data File identifying each NDC along with sourcing status of each drug: S, N, or I.

Table 2 - Generic Drug Utilization Data

	Single Source (S) Drugs	Non-Innovator (N) Drugs	Innovator Multi-Source (I) Drugs
Total Number of Claims	790,685	5,709,729	384,445
Total Reimbursement Amount Less Co-Pay	$740,671,604	$119,405,601	$125,431,438

Question	Response
3. Indicate the generic utilization percentage for all CODs paid during this reporting period, using the computation instructions in Table 2 – Generic Drug Utilization Data.	
Number of Generic Claims	5,709,729
Total Number of Claims	6,884,859
Generic Utilization Percentage	82.93%
4. How many multi-source drugs have the innovator as the preferred drug product based on net pricing?	**47**
5. Indicate the percentage dollars paid for generic CODs in relation to all COD claims paid during this reporting period using the computation instructions in Table 2: Generic Drug Utilization Data.	
Generic Dollars	$119,405,601
Total Dollars	$985,508,643
Generic Expenditure Percentage	12.12%
6. Does your state have any policies related to Biosimilars? Please explain.	**Colorado law allows pharmacists to substitute a prescribed biologic for a biosimilar that has been determined by the FDA to be interchangeable, provided that the prescriber has not indicated Dispense as Written on the order. Pharmacists must notify both the prescriber and the prescription purchaser of the substituted product. Reference biological products and biosimilars are managed on the PDL and Appendix P for the pharmacy benefit.**

Section VII – Program Evaluation / Cost Savings / Cost Avoidance

Question	Response
1. Did your state conduct a DUR program evaluation of the estimated cost savings/cost avoidance? If "Yes," identify, by name and type, the institution that conducted the program evaluation.	**Yes**
Institution Type	Company
Institution Name	Magellan Health, Inc
2. Please provide your ProDUR and RetroDUR program cost savings/cost avoidance in the chart below.	

	Data
ProDUR Total Estimated Avoided Costs	$706,785,058.74
RetroDUR Total Estimated Avoided Costs	$0.00
Other Cost Avoidance	$0.00
Grand Total Estimated Avoided Costs	$706,785,058.74

Question	Response
3. Estimated Percent Impact	**71.72%**
4. Summary 4 – Cost Savings/Cost Avoidance Methodology Summary 4 Cost Savings/Cost Avoidance Methodology includes program evaluations/cost savings estimates prepared by the state or contractor.	**Paid Claims Cost Avoidance is calculated by taking the paid dollar amount of claims with a ProDUR message that paid, but were subsequently reversed and subtracting the paid amount the claims resubmitted within 72 hours.** **(Claim Amount - Reversal Amount + Resubmit Amount)** **Denied Claims Cost Avoidance is calculated by taking the submitted dollar value of the claims that were initially denied and had a ProDUR message and subtracting any of those claims that were then resubmitted within the same calendar month and then paid.** **(Claim Amount - Resubmit Amount)** **ProDUR Total Estimated Avoided Costs = Denied Claims Cost Avoidance + Paid Claims Cost Avoidance**

Section VIII – Fraud, Waste, and Abuse Detection

A. Lock-In or Patient Review and Restriction Programs

Question	Response
1. Does your state have a documented process in place that identifies potential fraud or abuse of controlled drugs by beneficiaries?	**Yes**
If "Yes," what actions does this process initiate?	Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
Other, please explain.	N/A
2. Does your state have a Lock-In program for beneficiaries with potential misuse or abuse of controlled substances? If "Yes," please continue.	**Yes**
a. What criteria does your state use to identify candidates for Lock-In?	**Number of controlled substances (CS), Different prescribers of CS, Multiple pharmacies, Multiple ER visits**
Other, please explain.	N/A
b. Does your state have the capability to restrict the beneficiary to:	
i. Prescriber only	**Yes**
ii. Pharmacy only	**Yes**
iii. Prescriber and Pharmacy	**Yes**
c. What is the usual Lock-In time period?	**12 months**
Other, please explain.	N/A
d. On average, what percentage of the FFS population is in Lock-In status annually?	**0.0100%**
e. Please provide an estimate of the savings attributed to the Lock-In program for the fiscal year under review.	**$0.00**
3. Does your state have a documented process in place that identifies possible FWA of controlled drugs by prescribers?	**Yes**
Yes, what actions does this process initiate?	Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
Other, please explain.	N/A
No, please explain.	N/A
4. Does your state have a documented process in place that identifies potential FWA of controlled drugs by pharmacy providers?	**Yes**

Question	Response
Yes, what actions does this process initiate?	Refer to Program Integrity Unit (PIU) and/or Surveillance Utilization Review (SUR) Unit for audit/investigation
Other, please explain.	N/A
No, please explain.	N/A
5. Does your state have a documented process in place that identifies and/or prevents potential FWA of non-controlled drugs by beneficiaries?	**Yes**
Yes, please explain your program for FWA of non-controlled substances.	Retrospective DUR analyses and prior authorization are used to identify these issues. Beneficiaries are referred to the Program Integrity Unit that works with individual counties.
No, please explain.	N/A

B. Prescription Drug Monitoring Program (PDMP)

Note: Section 5042 of the SUPPORT for Patients and Communities Act requires states to report metrics in reference to their state's PDMP. CMS has included questions to reference these metrics to help your state establish processes to be in compliance with provisions outlined in Section 5042 and CMS reporting, beginning in FFY 2023.

Question	Response
1. Does your Medicaid program have the ability to query the state's PDMP database?	**No**
Yes, receive PDMP data.	N/A
Other, please explain.	N/A
Yes, have direct access to the database.	N/A
No, please explain.	The State is prohibited by law from accessing the PDMP. In our DUR criteria, we highly encourage providers to access the PDMP prior to prescribing any opioid, although pre-prescribing use of the PDMP is not required.
If "Yes," please continue. a. Please explain how the state applies this information to control FWA of controlled substances.	**N/A**
b. Does your state also have access to Border States' PDMP information?	**N/A**
c. Does your state also have PDMP data integrated into your POS edits?	**N/A**
2. Does your state or your professional board require prescribers to access the PDMP patient history before prescribing controlled substances?	**No**

Question	Response
No, please explain.	Colorado statute requires prescribers with a DEA number and Colorado license to establish and maintain a Colorado PDMP account. Pharmacists licensed in Colorado are also required to have and maintain PDMP user accounts. There is no requirement for prescribers to use the PDMP tool before prescribing controlled substances, although it is highly encouraged.
If "Yes," please continue. a. Are there protocols involved in checking the PDMP?	N/A
Yes, please explain.	N/A
b. Are providers required to have protocols for responses to information from the PDMP that is contradictory to the direction that the practitioner expects from the client?	**N/A**
c. If a provider is not able to conduct PDMP check, does your state require the prescriber to document a good faith effort, including the reasons why the provider was not able to conduct the check?	**N/A**
No, please explain.	N/A
If "Yes," does your state require the provider to submit, upon request, documentation to the State?	N/A
No, please explain.	N/A
3. Does the State require pharmacists to check the PDMP prior to dispensing?	**No**
No, please explain.	State statute does not require pharmacists to check the PDMP prior to dispensing, although this practice is highly encouraged, and may be required by specific pharmacist employers in the State.
If "Yes," are there protocols involved in checking the PDMP?	N/A
Yes, please explain.	N/A
4. In the State's PDMP system, which of the following pieces of information with respect to a beneficiary is available to prescribers as close to real-time as possible?	**PDMP drug history, The number and type of controlled substances prescribed to and dispensed to the beneficiary during at least the most recent 12-month period., The name, location, and contact information, or other identifying number, such as a national provider identifier, for previous beneficiary fills**
Other, please explain.	N/A

Question	Response
a. Are there barriers that hinder the Medicaid agency from fully accessing the PDMP that prevent the program from being utilized the way it was intended to be to curb FWA?	**Yes**
Yes, please explain the barriers (i.e. lag time in prescription data being submitted, prescribers not accessing, pharmacists unable to view prescription history before filling script).	The State is prohibited by legislation from accessing the PDMP. In our DUR criteria we highly encourage providers to access the PDMP prior to prescribing controlled substances.
5. Have you had any changes to your state's PDMP during this reporting period that have improved the Medicaid program's ability to access PDMP data?	**No**
Yes, please explain.	N/A
6. In this reporting period, have there been any data or privacy breaches of the PDMP or PDMP data?	**No**
If "Yes," please summarize the breach, the number of individuals impacted, a description of the steps the State has taken to address each such breach, and if law enforcement or the affected individuals were notified of the breach.	N/A

C. Opioids

Question	Response
1. Does your state currently have a POS edit in place to limit the quantity dispensed of an initial opioid prescription? If the answer to question 1 is "Yes, for all opioids" or "Yes, for some opioids," please continue.	**Yes, for all opioids**
Please explain answer above.	Opioid naive members are limited to short-acting opioids and quantities of 8 pills per day for up to a 7 day supply. Non-opioid naive members are limited to 4 pills per day of short-acting opioids for up to a 30 day supply. Long-acting opioids are subject to quantity limits listed on the preferred drug list (PDL) and are eligible for up to a 30 day supply. Dental prescriptions are limited to a three day supply of short-acting opioids.
a. Is there more than one quantity limit for various opioids? Additionally, please explain ramifications when addressing COVID-19 if applicable?	**Yes**

Question	Response
Yes, please explain.	Opioid naive members are limited to short-acting opioids and quantities of 8 pills per day for up to a 7 day supply. Non-opioid naive members are limited to 4 pills per day of short-acting opioids for up to a 30 day supply. Long-acting opioids are subject to quantity limits listed on the preferred drug list and are eligible for up to a 30 day supply. Dental prescriptions are limited to a three day supply of short-acting opioids. COVID-19 early refill policy implemented on 3/20/20 allowed pharmacies to enter POS overrides allowing early refill of opioids for circumstances related to COVID-19 with refill tolerance of > 50% previous fill utilized.
b. What is the maximum number of days allowed for an initial opioid prescription for an opioid naïve patient?	**7**
c. Does this days' supply limit apply to all opioid prescriptions?	**Yes, for some opioids**
Please explain above response.	The 7 day supply limitation for the first, second, and third fills of opioid prescriptions for opioid naive members applies to short-acting opioids. Prescriptions for long-acting opioids for opioid naive members require prior authorization. Dental prescriptions are limited to a 3 day supply of short-acting opioids for up to three fills.
2. For subsequent prescriptions, does your state have POS edits in place to limit the quantity dispensed of short-acting (SA) opioids?	**Yes**
Yes, what is your maximum days' supply per prescription limitation?	Other
Other, please explain.	Opioid naive members are limited to three 7 day supply prescriptions of short-acting opioids and require prior authorization for the fourth fill. Non-opioid naive members are limited to a 30 day supply per prescription fill. Dental prescriptions are limited to a three day supply of short-acting opioids for up to three fills.
No, please explain.	N/A

Question	Response
3. Does your state currently have POS edits in place to limit the quantity dispensed of long-acting (LA) opioids?	**Yes**
Yes, what is your maximum days' supply per prescription limitation?	30 day supply
Other, please explain.	N/A
No, please explain.	N/A
4. Does your state have measures other than restricted quantities and days' supply in place to either monitor or manage the prescribing of opioids?	**Yes**
If "Yes,":	Deny claim and require PA, Intervention letters, MME daily dose program, Step therapy or Clinical criteria, Requirement that prescriber has an opioid treatment plan for patients, Other
Other, please specify.	Prescriptions are limited to one long-acting opioid and one short-acting opioid Opioid-naive members are limited to short-acting opioids only.
Please provide details on these opioid prescribing controls in place.	Prescriptions are limited to one long-acting opioid (including different strengths) and one short-acting opioid (including different strengths) for opioid prior authorization approvals. Opioid-naive members are limited to short-acting opioids only. Prescriber opioid treatment plans are documented as part of provider-to-provider telephone consultations that are required for certain opioid prior authorizations.
If "No," please explain what you do in lieu of the above or why you do not have measures in place to either manage or monitor the prescribing of opioids.	N/A
5. Does your state have POS edits to monitor duplicate therapy of opioid prescriptions? This excludes regimens that include a single extended-release product and a breakthrough short acting agent?	**No**
Please explain above response.	Duplicate therapy limitations, including limit of one long-acting opioid (including different strengths) and one short-acting opioid (including different strengths) for concomitant use, are managed by limiting PA approval on file for opioid medications prescribed.

Question	Response
6. Does your state have POS edits and automated retrospective claim reviews to monitor early refills of opioid prescriptions dispensed?	**Yes, both POS edits and automated retrospective claim reviews**
If any response is "Yes," please explain scope and nature of reviews and edits in place.	All opioid claims are subject to 85% early refill tolerance and a cumulative total of 20 early refill days over a 180 day period. An early refill policy was implemented during 3/20/20-9/25/20 that permitted pharmacies to enter POS overrides allowing early refill of opioids for circumstances related to COVID-19 with refill tolerance of > 50% previous fill utilized.
If "No," please explain.	N/A
7. Does your state have a comprehensive automated retrospective claims review process to monitor opioid prescriptions exceeding these state limitations?	**Yes**
Yes, please explain in detail scope and nature of these retrospective reviews.	Retrospective review is conducted on a case-by-case basis at the claims level as part of a Prior Authorization requirement triggered by MME > 200mg or the 4th fill of an opioid for a previously opioid-naive member or the 4th fill of an opioid prescribed by a dental provider.
No, please explain.	N/A
8. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and benzodiazepines being used concurrently?	**Yes, both POS edits and automated retrospective claim reviews**
Please explain above response and detail the scope and nature of these reviews and edits. Additionally, please explain any potential titration processes utilized for those patients chronically on benzodiazepines and how the state justifies pain medications, i.e. Oxycodone/APAP, for breakthrough pain without jeopardizing patient care (i.e. quantity limits/practitioner education titration programs).	ProDUR alert systems edits are in place when concomitant opioid and benzodiazepine claims are submitted. Automated retrospective review of claims history identifies long-term use of either an opioid or benzodiazepine medication, and subsequent claims submitted for the respective concomitant medication will then deny for PA required. Retrospective DUR is also conducted and letters are sent to providers regarding member concomitant use of these medications.
No, please explain.	N/A

Question	Response
9. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and sedatives being used concurrently?	**No**
Please explain above and detail scope and nature of reviews and edits.	N/A
No, please explain.	There are no edits in place for opioids and sedatives at this time.
10. Does your state currently have POS edits in place or automated retrospective claims review to monitor opioids and antipsychotics being used concurrently?	**Yes, POS edits**
Please explain in detail scope and nature of reviews and edits.	Due to the risk of increased sedation with concomitant use, pharmacy claims for members receiving an opioid and quetiapine in combination require entry of POS DUR service codes (Reason for Service, Professional Service, Result of Service) in order to override an opioid-quetiapine drug-drug interaction.
No, please explain.	N/A
11. Does your state have POS safety edits or perform automated retrospective claim reviews and/or provider education in regard to beneficiaries with a diagnosis history of opioid use disorder (OUD) or opioid poisoning diagnosis?	**No**
If "Yes, Automated retrospective claims reviews and/or "provider education," please indicate how often.	N/A
Other, please specify.	N/A
Please explain nature and scope of edits, reviews and/or provider education reviews performed.	N/A
If "No," does your state plan on implementing automated retrospective claim reviews and/or provider education in regard to beneficiaries with a diagnosis history of OUD or opioid poisoning in the future?	Yes
Yes, when does your state plan on implementing?	Implemented during FFY 2021 (after this reporting period)
No, please explain.	N/A
12. Does your state Medicaid program develop and provide prescribers with pain management or opioid prescribing guidelines?	**Yes**
If "Yes," please.	Your state Medicaid program refers prescribers to the Center for Disease Control

Question	Response
	(CDC) Guideline for Prescribing Opioids for Chronic Pain., Other guidelines.
Other guidelines, please identify.	Washington State Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Colorado Dental Board, Colorado Medical Board, State Board of Nursing, and State Board of Pharmacy, Policy for Prescribing and Dispensing Opioids; State developed policies for opioid use.
If "No," please explain why no guidelines are offered.	N/A
13. Does your state have a drug utilization management strategy that supports abuse deterrent opioid use to prevent opioid misuse and abuse (i.e. presence of an abuse deterrent opioid with preferred status on your preferred drug list)?	**Yes**
Yes, please explain.	Preferred status of Embeda (morphine sulfate/naltrexone) during reporting period.

D. Morphine Milligram Equivalent (MME) Daily Dose

Question	Response
1. Have you set recommended maximum MME daily dose measures?	**Yes**
If "Yes," please continue.	
a. What is your maximum morphine equivalent daily dose limit in milligrams?	**200 MME mg per day**
Less than 50 MME, please specify.	N/A mg per day
Greater than 200 MME, please specify.	N/A mg per day
b. Please explain nature and scope of dose limit (i.e. who does this edit apply to? Does the limit apply to all opioids? Are you in the process of tapering patients to achieve this limit?).	**Prior authorization involving prescriber-to-prescriber consult is required for members' prescriptions that exceed the MME limit. An opioid prescribing plan and recommendations for tapering are documented as part of this consult and approval may be placed to allow for tapering.**
If "No," please explain the measure or program you utilize.	N/A
2. Does your state have an edit in your POS system that alerts the pharmacy provider that the MME daily dose prescribed has been exceeded?	**Yes**
If "Yes," does your state require PA if the MME limit is exceeded.	Yes

Question	Response
3. Does your state have automated retrospective claim reviews to monitor the MME total daily dose of opioid prescriptions dispensed?	**Yes**
Please explain.	Magellan Health, Inc., the point of service vendor, calculates the cumulative MME across opioid prescription claims processed for individual members.
4. Do you provide information to your prescribers on how to calculate the morphine equivalent daily dosage or do you provide a calculator developed elsewhere? If "Yes," please continue.	**Yes**
a. Please name the developer of the calculator:	**Other**
Other, please specify.	Washington State Agency Medical Directors' Group
b. How is the information disseminated?	**Website**
Other, please explain.	N/A

E. Opioid Use Disorder (OUD) Treatment

Question	Response
1. Does your state have utilization controls (i.e. PDL, PA, QL) to either monitor or manage the prescribing of Medication Assisted Treatment (MAT) drugs for OUD?	**Yes**
Yes, please explain.	**Prescribers may request assistance with pain management strategies and/or the use of MAT drugs for OUD through the peer-to-peer Health First Colorado Pain Consultation Service. Greater than four prescription fills of an opioid for a previously opioid naive member may require a telephone consultation with a pain management physician.**
2. Does your Medicaid program set total mg per day limits on the use of buprenorphine and buprenorphine/naloxone combination drugs?	**Yes**
If "Yes," please specify the total mg/day:	24 mg
Other, please explain.	N/A
3. What are your limitations on the allowable length of this treatment?	**No limit**
Other, please explain.	N/A

Question	Response
4. Does your state require that the maximum mg per day allowable be reduced after a set period of time? If "Yes," please continue.	**No**
a. What is your reduced (maintenance) dosage?	**N/A**
Other, please explain.	N/A
b. What are your limitations on the allowable length of the reduced dosage treatment?	**N/A**
Other, please explain.	N/A
5. Does your state have at least one buprenorphine/naloxone combination product available without PA?	**No**
6. Does your state currently have edits in place to monitor opioids being used concurrently with any buprenorphine drug or any form of MAT?	**Yes**
Other, please explain.	N/A
If "Yes," can the POS pharmacist override the edit?	No
7. Is there at least one formulation of naltrexone for OUD available without PA?	**Yes**
8. Does your state have at least one naloxone opioid overdose product available without PA?	**Yes**
9. Does your state retrospectively monitor and manage appropriate use of naloxone to persons at risk of overdose?	**No**
No, please explain.	Retrospective analysis and monitoring of naloxone utilization among members at risk for overdose conducted after the FFY 2020 reporting period.
10. Does your State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid program allow pharmacists to dispense naloxone prescribed independently or by collaborative practice agreements, standing orders, or other predetermined protocols?	**Yes, State Board of Professional Regulations/Board of Pharmacy/Board of Medicine and/or state Medicaid program under protocol**

F. Outpatient Treatment Programs (OTP)

Question	Response
1. Does your state cover OTPs that provide Behavioral Health (BH) and MAT services?	**Yes**
No, please explain.	N/A
If "Yes", is a referral needed for OUD treatment through OTPs?	Yes
Please explain.	Reimbursement for services is authorized by Regional Accountable Entities (RAEs) (regional agents administering the State's Medicaid SUD benefit) with submission of an SUD authorization form by qualified providers.
2. Does your state Medicaid program cover buprenorphine or buprenorphine/naloxone for diagnoses of OUD as part of a comprehensive MAT treatment plan through OTPs?	**Yes**
No, please explain.	N/A
3. Does your state Medicaid program cover naltrexone for diagnoses of OUD as part of a comprehensive MAT treatment plan?	**Yes**
No, please explain.	N/A
4. Does your state Medicaid program cover Methadone for a substance use disorder (i.e. OTPs, Methadone Clinics)?	**Yes**

G. Antipsychotics / Stimulants

Antipsychotics

Question	Response
1. Does your state currently have restrictions in place to limit the quantity of antipsychotics?	**Yes**
Please explain restrictions or N/A.	Quantity and age limits are in place.
2. Does your state have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children? If "Yes," please continue.	**Yes**
a. Does your state either manage or monitor:	**All children**
Other, please explain.	N/A
b. Does your state have edits in place to monitor:	**Child's age, Dosage, Indication**
Other please explain.	N/A

Question	Response
c. Please briefly explain the specifics of your documented antipsychotic monitoring program(s).	**Edits are in place to identify doses exceeding maximum and off-label uses based on atypical antipsychotic indications for use and patient age, and require prior authorization potentially involving a child/adolescent psychiatrist consult. Retrospective DUR is conducted and letters are sent to providers regarding pediatric members' use of antipsychotic medications.**
If "No," does your state plan on implementing a program in the future.	N/A
Yes, please specify when you plan on implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A
No, please explain why you will not be implementing a program to monitor the appropriate use of antipsychotic drugs in children.	N/A

Stimulants

Question	Response
3. Does your state currently have restrictions in place to limit the quantity of stimulants?	**Yes**
4. Does your state have a documented program in place to either manage or monitor the appropriate use of stimulant drugs in children? If "Yes," please continue.	**Yes**
a. Does your state either manage or monitor:	**Other**
Other, please explain.	All children are managed/monitored. Additionally, edits are in place for maximum dose, off-label use, and patient age. Prior authorization may be required when exceeding limitations.
b. Does your state have edits in place to monitor:	**Child's age, Dosage, Indication**
Other, please explain.	N/A
c. Please briefly explain the specifics of your documented stimulant monitoring program(s).	**Edits are in place for maximum dose, off-label use, and patient age. Prior authorization and expanded clinical review by a pharmacist may be required when exceeding limitations.**
If "No," does your state plan on implementing a program in the future?	N/A
Yes, please specify when you plan on implementing a program to monitor the appropriate use of stimulant drugs in children.	N/A

Question	Response
No, please explain why you will not be implementing a program to monitor the appropriate use of stimulant drugs in children.	N/A

Section IX – Innovative Practices

Question	Response
1. Does your state participate in any demonstrations or have any waivers to allow importation of certain drugs from Canada or other countries that are versions of FDA-approved drugs for dispensing to Medicaid beneficiaries?	**Yes**
Yes, please explain.	The Colorado General Assembly passed legislation in 2019 authorizing the importation of certain drugs from eligible Canadian suppliers.
2. Summary 5 – Innovative Practices Summary 5: Innovative Practices should discuss development of innovative practices during the past year (i.e. Substance Use Disorder, Hepatitis C, Cystic Fibrosis, MME, and Value Based Purchasing).	**As part of the State's contract with the CU Skaggs School of Pharmacy and Pharmaceutical Sciences, clinical modules are conducted every quarter to provide a deeper granular evaluation of medication related issues and programmatic policies that are pertinent to our members. We use these data to make both policy changes as well as improve the medication safety and quality of life for our members. Below are the summaries of five evaluations conducted during FFY 2020. Detailed reports are available upon request.** **Consult Service Clinical Outcomes Investigation: Pain Management Specialty (Delivered 10/29/2019)** **Objectives:** **Describe members participating in the Opioid Consult Service** **OUTCOMES: The largest Consult Service group was opioid naive (n=268), followed by high dose opioid users (n=74) and provider-initiated (n=18). Slightly more than half of the high dose opioid users group (51.35%) was female while less than half of the opioid naive group (46.18%) was female. The majority of members in each Consult Service group reported being White or multiple race/ethnicities. The mean age was highest in the high dose opioid use group (49 years), and lowest in the opioid naive group (45 years).** **Estimate the effect of the Opioid Consult Service on opioid use** **OUTCOMES: Among members who received a high dose opioid use consult, there were improvements in several outcomes when**

Question	Response
	compared between the three months prior to the consult and the three months following the consult **Fewer members had an average MME greater than/equal to 200 during the three months following their consult (80.9%) compared to the three months before (88.8%); 76% had an average MME greater than/equal to 200 both prior to and following their consult, while 7.9% had an average MME < 200 both prior to and following their consult. Over 11% improved, having an average MME greater than/equal to 200 prior to their consult and an average MME < 200 following their consult. Use of atypical opioids (defined as tapentedol, tramadol, or buprenorphine product formulations) and high risk medications (defined as an add-on muscle relaxant or benzodiazepine) decreased following the consult. Almost 13% of members discontinued use of high risk medications after their consult; 6% of members discontinued use of atypical opioids. However, all-cause hospital and ER visits increased slightly.** **Similar trends were seen when the pre and post periods were expanded to six months. Seventeen percent of members had an average MME greater than/equal to 200 during the six months prior to their consult and an average MME <200 following their consult. Use of atypical opioids and high risk medications decreased following the consult. Almost 11 percent of members discontinued use of high risk medications after their consult; 7 percent of members discontinued use of atypical opioids. All-cause hospital and ER visits stayed about the same.** **In the high dose opioid use group, there was a significant decrease in average MME for both the three month pre to post comparison and the six month pre to post comparison. Average MME decreased from a median of 286.61 during the three months prior to a consult to 268.94 during the three months following a consult (absolute change = -25.43, percent change = -7.48%). The decrease was more substantial when compared between**

Question	Response
	the six months before a consult to the six months following a consult, with a median difference of -43.02 (percent change = -12.53%). The median total opioid doses decreased from three months pre consult to three months post consult, but the differences were not statistically significant. The change from six months pre consult to six months post consult was larger, but also not significant: the median total opioid dose decreased from 1020 during the six months prior to a consult to 865 during the six months following a consult (absolute median change = 1.00, median percent change = 0%). **Use of high risk medications among the opioid naive consult group decreased from 34% during the three months prior to the consult to 26% during the three months following the consult; 16% discontinued use of high risk medications following their consult. Use of atypical opioids and long-acting opioids increased from the pre-period to post-period; it is important to note that use during the pre-period is indicative of the type of opioid the member was initiated on because by definition, the opioid naive group would not have used an opioid prior to the initiation that flagged the consult. More than half of the members did not use atypical opioids during the pre or post-period; 88% of members did not use long-acting opioids during the pre or post-period.** **All-cause hospital and ER visits decreased following consults; 34% of members had a hospital/ER visit during the three months prior to their consults but had no visits during the three months following their consult. Similar results were seen when the pre and post periods were expanded to six months. Of note, 18% discontinued use of high risk medications during the six months following their consult. Almost 14% discontinued use of an atypical opioid in the six months following their consults. All-cause hospitalizations and ER visits also decreased.** **Among the cohort of opioid naive members who received a consult and had at least three months of enrollment following their consult**

Question	Response
	(n=229), the percentage of members continuing opioid medication decreased from 36% during the 30 days following the consult to 26% during the first 90 days following the consult. In other words, 74% had discontinued the opioid by 90 days following their consult. In comparison, the historical opioid naive group with three months of follow-up (n=4,167) saw a similar downward trend in opioid continuation. However, the prevalence of opioid use was higher within each time period compared to the opioid naive consult cohort, starting at 41% of members using an opioid during the 30 days following their proxy consult and decreasing to 33% by 90 days following their proxy consult. **In order to look further than three months, we considered the sub-cohorts with at least six months of enrollment following their consult. Opioid use continued to decrease in both the opioid naive consult group (n=185) and in the historical opioid naive group (n=3,092) through 180 days following their consults.** **Discussion:** **For this analysis, the CO-DUR team divided all of the consults that were conducted between February 2017 and April 2019 and split them into 3 groups depending on their type. The three groups identified are high dose, opioid naive, and provider requested.** **The largest group of consults was the opioid naive group with 268 total consults, followed by high dose opioids with 78 total consults, and 18 provider requested consults. Different sets of outcomes were measured in each opioid naive and high dose opioid group as the goals of the consult are different for each setting. Both outcome sets include concomitant high risk medication prescribing. A duration of opioid therapy was measured in the opioid naive group and a decrease of MME with total dosage count was measured in the high dose group. An outcome of atypical opioid proportion prescribed was also measured in the high dose group. The high dose group and the opioid naive groups**

Question	Response
	were then used to conduct two separate investigations. One investigation looked at the outcome set six months before and six months after the consult index time. The other investigation looked at the outcome set 3 months before and 3 months after the consult index time. **Our findings show a similar sex and other measured demographic breakdown amongst opioid naive and high dose opioid groups. The provider-requested consult group is small (n=18) and has slightly different demographic distributions. For the high dose group, the findings are positive for MME <200 and reduction of proportion of atypical opioid prescribed in both the 3 month and the 6 month test groups.** **As the consultant routinely recommends atypical opioids, we wrongly hypothesized that the proportion would go up. In both the 3 and 6 month high dose the number of ED visits remained about the same. A decrease in this number is a central goal of opioid policy as a surrogate marker of overdose visits. While there was an absolute decrease in the number of high-risk medications prescribed with the high dose group in the 3 and 6 month sub-groups, this did not approach statistical significance. With the nature of high risk concomitant prescribing with opioids, all reductions may be clinically significant.** **Our findings show absolute reductions in MME and total dose counts, with statistical findings in both groups. There is some heterogeneity of members who may have had a decrease in MME, but an increase in dosage forms prescribed. Those particular members are being prescribed more dosage forms of a lower dosage opioid and the percent change is positive for this reason. With some control for outliers, this would likely be negative as hypothesized.** **For the opioid naive portions of the module, our findings show a positive and statistically significant decrease in high risk concomitant prescribing at both 3 and 6 month sub-groups. Policy limiting these high risk**

Question	Response
	combinations are not yet implemented, but the RDUR program has been providing letters to providers regarding the 3 part combination of an opioid, a BZD, and a skeletal muscle relaxant for the past year. Strong warnings from the CDC and other entities plus our own local RDUR projects may influence some of these results. Hospital and ED visits significantly decreased in the opioid naive group for the 3 and 6 month tests. Many of the members included in the opioid naive group may have received their acute opioid prescription immediately following a hospitalization or ED visit, which could have influenced this reduction. **Recommendations:** **Continue and, if possible, expand the pain management consult service. Future potential triggers include combination opioid and benzodiazepine prescribing as well as risk factor stratification.** **Outcomes analysis for Child Psychiatry Specialty Consult service (Delivered 12/19/19)** **Objectives:** **Describe members participating in the Child Psychiatry Consult Service Population** **OUTCOMES: The largest Child Psychiatry Consult Service group was flagged for off-label age for antipsychotic medications (n=192), followed by off-label dosing for psychostimulants (n=80) and provider-initiated (n=6). The majority of each group were not in foster care at the time of their index consult (78% - 87%). While the provider-initiated consult group was primarily female (83%), there were more males than females in the other two consult groups. The majority of members in each Child Psychiatry Consult Service group reported being White or multiple race/ethnicities. The mean age was highest in the provider-initiated group (mean = 13.8 years) and lowest in the off-label dosing for psychostimulants group (mean = 8 years). Age ranged from 3 to 17 years in each group. The most common mental health diagnoses**

Question	Response
	received by members flagged for a consult because of off-label age for antipsychotic or off-label psychostimulant dosing during the three months prior to the consult were from the following categories: Behavioral and emotional disorders with onset usually occurring in childhood and adolescence; pervasive and specific developmental disorders; anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders; and mood [affective] disorders. The most common diagnosis among members with a provider-initiated consult was a mood [affective] disorder **Describe the effect of Child Psychiatry Consult Service on outcomes** **OUTCOMES: Among members who received a consult for off-label for age antipsychotic medications, there were improvements in some outcomes when compared between the three/six months prior to the consult and the three/six months following the consult. While more members used off-label antipsychotics during the three and six months following their consult compared to prior to their consult, use of multiple stimulants decreased from 12.6% in the three months prior to 9.6% in the three months post. Supramaximal use of antipsychotics and stimulants was very low prior to and following consults.** **Several discrete (i.e., count) outcomes significantly decreased from the three/six month prior to the consult to the three/six months following the consult. The number of distinct stimulants and outpatient visits (all-cause) significantly decreased from the three months pre to the three months post-consult. When the pre and post time periods were extended to six months, several more outcomes saw a significant improvement. Count of distinct drugs, distinct psychotropics, distinct stimulants, and outpatient visits (all-cause and mental health related) all significantly decreased from the six months prior to the consult to the six months following the consult.** **Small changes were seen among members**

Question	Response
	who received a consult for off-label dosing for psychostimulant medications. Use of multiple stimulants increased from the three/six months prior to the consult to the three/six months following the consult, while supramaximal stimulant use slightly decreased. No changes were statistically significant. **Several discrete (i.e., count) outcomes significantly increased from the three/six month prior to the consult to the three/six months following the consult. The number of distinct stimulants and distinct psychotropics significantly increased from the three months pre to the three months post-consult. When the pre and post time periods were extended to six months, the count of distinct psychotropics, distinct stimulants, and inpatient visits (all-cause) significantly increased from the six months prior to the consult to the six months following the consult.** **Examine trends in receipt of antipsychotics in children younger than 5** **OUTCOMES: The start of the Child Psychiatry Consult Service began in February 2017. When taking into account the number of antipsychotic medication fills in children less than 5 years of age, trends suggest a sharp drop of 7 fills in September 2016 to 3 fills one year later. While an increase in fills was demonstrated in January 2018 to 8, these have dropped to between 2-3 fills during the study period following implantation of the consult service.** **Discussion:** **Off-label age for antipsychotic medication was the largest consult group with 192 recorded consults, followed by off-label dosing of a stimulant medication with 80 recorded consults and lastly there were six recorded provider-initiated consults. Approximately two-thirds of all members consulted upon were male and approximately 40% identified as either white race or multiple race making the vast majority of reported race.**

Question	Response
	Off-label age for antipsychotic has a very different age distribution for the consulted cases than the off-label dose for a stimulant group does with the smallest group being age range 0-5 years old. The off-label age for antipsychotic group also has a higher percentage of members identified as receiving foster care. There are not currently antipsychotic medications indicated for use by the FDA in patients 5 years of age or under, but about 12% of this consult cohort were in this age group. **The foster care population representing a higher percentage of members receiving antipsychotics versus stimulants may be due to higher needs and much different mental health demographics of the foster population.** **In attempt to further define the population of who is being triggered for consult, the number of diagnoses in each consult group was collected and organized by groups of ICD-10 codes. Behavioral and emotional disorders with onset usually occurring in childhood and adolescence and pervasive and specific developmental disorders comprise the majority of mental health diagnoses that were given to the cohorts in the pre-phase. Behavioral and emotional disorders with onset usually occurring in childhood and adolescence includes diagnoses of attention deficit hyperactivity disorder (ADHD), conduct disorders, tics, stuttering, and many more. Pervasive and specific developmental disorders includes autism, Asperger's Syndrome disintegrative disorder, Rett's Syndrome, and many more.** **The off-label prescribing appears to increase significantly in both the three and six month cohorts. This is probably related to first time antipsychotic prescriptions being written in which a member was naive to the antipsychotics measured. The outcome of multiple stimulants was measured in this group and a significant decrease is found in**

Question	Response
	both three and six month cohorts. For discrete outcomes analyzed, multiple outcomes in the six month cohort showed significant decreases including Distinct Drugs (By name, Dose), Distinct Psychotropics (By Drug ID), Distinct Stimulants (By Drug ID), Outpatient visits (all cause), and Outpatient visits (mental health). Not all of these outcomes were found to be statistically significant in the three month cohort, suggesting that it may take a few months to realize the benefits of the consult. Psychotropic medication tapering and switching does take time depending on the situation and could take up to a couple months to titrate a new medication to therapeutic range safely. **In terms of off-label dosing of a stimulant consult cohort, there was no impact on high dose prescribing or multiple stimulant use in both the three and six month cohorts. We theorized there would be downward trends with these outcomes. The multiple stimulant outcome required a 50% overlap and controlled for immediate release and extended release formulations of the same medication being taken (this would count as one stimulant). These results suggest further expansion of stimulant prescribing should be conducted to determine why the consult service has not had impact. For discrete outcomes analyzed, a notably significant increase was found in Distinct Psychotropics (By Drug ID), Distinct stimulants (By Drug ID), and inpatient hospital stays (all cause). For the increases in psychotropic medication and stimulants, the outcomes are likely measuring members who were previously naive to a stimulant. Also, in the psychotropic medication group, stimulants are included, which produces a duplicate measure but important outcome of total psychotropic medications, but for this reason both outcomes could trend in a similar manner. Some of the increase in all cause hospitalizations may be related to the recent increase in psychotropic medications and**

Question	Response
	subsequent risk for adverse event. **Our third objective quantified the outcome of antipsychotic fills for members younger than 5 years prior to and following implementation of the consult service in February 2017. However, the monthly count of fills (<10 each month) is too small to determine meaningful trends. Ideally, the members who were flagged for their provider to receive a consult through the Child Psychiatry Consult Service (i.e., the off-label age for antipsychotic medications group and off-label dosing for psychostimulants group) could be compared to a control group that was not flagged to receive a consult. In order to make such comparisons, the control group would need to be as similar as possible to the groups that were flagged to receive a consult. Creation of such a control group is not possible once the consult service was implemented because all members meeting the criteria to trigger the service (i.e., off-label age for antipsychotic medications and off-label dosing for psychostimulants) would inherently become one of the consult groups. Members who did not meet the criteria would be too different from those that did, particularly regarding antipsychotic use, making them an inappropriate control group.** **Upon review of consult notes for the multiple antipsychotics cohort. Intentional multiple antipsychotic prescribing was found to be very low and clinical notes show 1 of the 3 members receiving concomitant therapy had basal antipsychotic coverage in addition to as needed dosing for severe symptoms. Consultants approved all but 1 medication triggering consult (28 out of 29 reviewed). This population was found to have severe symptoms across the board with agitation, aggression, hallucinations, psychotics disorders, and severe symptoms with autism spectrum disorders found.** **The six month off-label antipsychotic group shows some promising preliminary numbers**

Question	Response
	with regard to impact of the consult service. The off-label dose for stimulant group likely requires expanding and adjusting the approach by which clinical outcomes are measured. **Recommendations: Add more than one antipsychotic to list of consult triggers for pediatric members, more antipsychotics are gaining pediatric indications potentially resulting in multiple antipsychotic prescribing that is not triggering for below minimum age. Use a strict definition for more than one antipsychotic. Second, work with child and adolescent psychiatry consultants to determine continued appropriateness of current triggers. Finally, consider other patient factors such as developmental disorders when consulting specialist and include other health conditions in consult form.** **Calcitonin Gene-Related Peptide Antagonists Utilization Review (Delivered 3/31/20)** **Objectives:** **Describe members receiving CGRP antagonist** **OUTCOMES: Nearly half of the members who filled at least one CGRP antagonist from August 2018 through September 2019 (N=973) filled Aimovig (45%), while 44% filled Emgality and the remaining 11% filled Ajovy. The large majority of each group was female (84% - 88%) and white (51% - 58%). The mean age was about 40 years old in each group, with about half of the members (47%) in the 36 to 50 years age group. Nearly all members (approximately 96%) had a diagnosis of migraine at some point during the two years prior to their initial CGRP fill, while only about 1% had a prior diagnosis of episodic cluster headache. Members had similar lengths of prior enrollment (an average of 48 to 53 months), indicating adequate time prior to their first CGRP to consider related diagnoses, migraine-related medication use, and health service utilization use.** **Describe CGRP antagonist utilization**

Question	Response
	OUTCOMES: The large majority of the CGRP antagonist cohort (90%) filled only one type of CGRP antagonist; 10% filled two and less than 1% filled all three. Duration of CGRP antagoinist use ranged from 28 days to 457 days (mean = 133 days). Adherence was fairly high (75%). About half of the cohort (50%) had concomitant use of an abortive agent, while 26% had concomitant use of a preventative agent. Thirty-percent used Botox concomitantly. Prior to filling the initial CGRP antagonist, the average number of fills of a preventative agent was 1.7 (range 0-9). Among members with at least one Emgality fill (N=427), the majority had no loading doses (70%); 29% had one loading dose; and less than 1% had two or three loading doses. The abortive agents most commonly used with a CGRP antagonist were sumatriptan (34%) and rizatriptan (23%). The Preventative agents most commonly used with a CGRP were topiramate (33%) and amitriptyline (21%). The total monthly counts of CGRP fills from June 2018 through September 2019 shows an upward trend until August 2019. It is likely that the slight decrease between August and September2019 is due to a lag in data availability for September 2019. October through December 2019 are not provided as they were not included in the analysis. **Examine impact of CGRP antagonist use on migraine-related medication use and health services utilization** **OUTCOMES: Among a subcohort of members who filled a CGRP at least twice, fewer members filled an abortive agent after starting a CGRP; the same was true for preventative agents. However, days covered by abortive agents and preventative agents significantly increased from the pre-period to the post-period. Mean total days covered by abortive agents was about 4 days longer in the post-period compared to the pre-period; mean total days covered by preventative agents was about one week longer.** **Among this same subcohort, fewer patients had an emergency department (ED) visit and fewer had a hospital visit during the post-**

Question	Response
	period compared to the pre-period. The mean number of ED visits and hospital visits was less than one in each period and did not significantly change from the pre-period to the post-period. **Discussion:** **The members receiving CGRP inhibitors are majority female with age ranging from 16 years to 71 years of age. The age group 36-50 years appears to be receiving the most CGRP inhibitor prescriptions. The racial distribution does not differ in any of the different medication groups. 95% of members receiving a CGRP inhibitor have a diagnosis of migraine headaches, while 1% has a diagnosis of cluster headache.** **The remaining members likely were placed on Aimovig when it was available and unmanaged after the class initially came to market. Most members (~90%) taking a CGRP inhibitor have only taken one and approximately 10% have trialed two. Switching may be due to adverse effects, lack of efficacy, or criteria/preferred coverage changes. About 50% of members were found to be taking a concomitant abortive agent and ~26% taking another preventative agent. 70.5% of Emgality users have no evidence of receiving a loading dose. A loading dose is indicated in the labeling for Emgality and low adherence with loading may be a provider education issue. The members may also be receiving the loading dose in the provider's office, which would not show up in pharmacy claims.** **Also, if the provider was administering the loading dose from a sample provided by industry, this may not show up as a pharmacy claim or a j-code. A trend of increased CGRP inhibitor claims per month was observed, but this is not a surprising finding given that these medications are new and represent a new mechanism for a disease state that affects ~10% of the general population.**

Question	Response
	Using current PDL PA criteria, we also determined the maximum number of Medicaid members who would be eligible to receive a CGRP antagonist for migraine headaches (since episodic cluster headaches represent a small portion of the population). There is an ICD-10 code for chronic migraines, but not for episodic migraine, thus limiting the strength of this approach. Our teams' approach chose the family ICD-10 for migraine headache and the sub-code for chronic migraine. Based on a large survey of patients experiencing migraines in 2006-200711, 7.7% of participants who had previous year history of migraine, met diagnostic criteria for chronic migraine. **The portion of their population who had episodic migraine was higher than chronic migraine, but comparable numbers were not provided. Authors also noted that approximately 63% of survey responders had 1-4 migraines per month. Pulling the ICD-10 code for chronic migraine from the Medicaid dataset returned nearly 12 thousand unique members, suggesting a higher rate of chronic migraine diagnosis among those with a diagnosis of migraine headache. The limitation step of medication overuse headache with chronic migraine to determine CGRP antagonist eligibility is softening as literature evolves.** **The PDL, effective 4/1/2020, contains language for the use of Aimovig for members with medication overuse headache. This step in the way we have counted CGRP eligibility limits about 48,000 members. Aimovig is the only CGRP with literature supporting efficacy in medication overuse headache at this time, and since this diagnosis was found in such a large portion of the population, one would expect Aimovig utilization to outpace the other CGRP antagonists. Piecing together the chronic migraine population, projected episodic migraine population, and adding in some tolerance for medication overuse headache, we predict the maximum**

Question	Response
	utilization of CGRP antagonists with the current criteria to be somewhere around 10-12,000 members. That's 9-11,000 additional members taking a CGRP inhibitor. **Regarding abortive and preventative medication utilization among members receiving a CGRP inhibitor, fewer members were found to be receiving either during the post measurement period. But with fewer members receiving either medications, it was found that more days-supply of both abortive and preventative medications were being provided. This may be resulting from an acute destabilization of migraine symptoms of some members with starting a new anti-migraine therapy resulting in the necessity for extra coverage. It may also be an artifact in the analysis showing that at the time of prescription of the CGRP inhibitor, other medications were also prescribed. No statistically significant difference was measured in the number of emergency department visits or hospital visits.** **Botox utilization stayed and remained relatively high prior to and after initiating a CGRP inhibitor. Members potentially had not had a chance to trial off of Botox after starting the CGRP inhibitor. Overall, a benefit measured in the outcomes of medication use and medical resource utilization found no positive impact. More outcomes may be conducted to investigate further and as time elapses, the measurement sample will grow, strengthening and potentially changing results.** **Recommendations: First, maintain criteria that requires migraine headache monthly counts. Could streamline reauthorization criteria after initial period to determine efficacy to same for all indications. Second, add educational information to PDL regarding loading dose of Emgality. Third, continue to monitor concomitant Botox and CGRP antagonist use, while not overtly inappropriate, there may be less appropriate**

Question	Response
	circumstances for use. Potentially use RDUR to inform providers and/or suggest trial off of Botox while CGRP is being used. Finally, maintain familiarity with medication overuse headache and emerging literature investigating safety/efficacy of CGRP inhibitors. **Proton Pump Inhibitor (PPI) therapy duration quality analysis: post policy change implemented 1/1/2019 (Delivered 6/30/2020)** **Objectives:** **Describe members receiving a PPI prior to and following the policy change in January 2019** **OUTCOMES: The majority (61-62%) of members filling PPIs in 2018 and 2019 were female, and the average age was 41 years (median = 43 years). Nearly 70% of the members filling a PPI had a GERD diagnosis on or since January 1, 2016. Besides GERD, gastritis/duodenitis (ICD10 code K29) was the most common esophagus, stomach and duodenum diagnosis among members filling a PPI (22.65% in 2018, 21.44% in 2019), followed by other diseases of stomach and duodenum (ICD10 code K31), other disease of esophagus (ICD10 code K22), esophagitis (ICD10 code K20), and gastric ulcer (K25). The most common diagnoses of the esophagus, stomach and duodenum were the same among members with at least one PPI fill and no GERD diagnosis, although with slightly lower prevalence of each diagnosis among the group of members with no GERD diagnosis.** **Investigate the impact of the January 1, 2019 policy change on PPI and H2RA utilization, therapy duration and associated outcomes** **OUTCOMES: The total number of members who filled an H2RA and the total number of H2RA claims decreased from 2018 to 2019, while the total number of members who filled a PPI and the total number of PPI claims increased from 2018 to 2019. Mean days supplied increased from 2018 to 2019 for**

Question	Response
	both H2RAs and PPIs (more so for PPIs). Mean days supplied ranged from 44-44 days for H2RAs, and from 42-46 days for PPIs. Mean doses per day were approximately 1 per day for PPIs and 2 per day for H2RAs. Doses per day slightly increased from 2018 to 2019 for H2RAs and slightly decreased for PPIs. **PPI twice-daily dosing decreased from 31.6% in 2018 to 25.8% in 2019. The number of PPI starts stayed stable from 2018 to 2019, with approximately 75% of members having only 1 start of a PPI, 21% with 2 PPI starts, and 4% having 3 or more starts. Note that nearly 60% of patients with a PPI in 2019 had no new starts; rather, they had a PPI fill late in 2018 that overlapped January 1, 2019. The percentage of members with continuous PPI use increased from 57% in 2018 to 67% in 2019. Average length of first continuous PPI use increased from 91 days in 2018 to 120 days in 2019; the average length of continuous PPI use increased from 91 days to 106 days. PPI days covered increased from 110 days in 2018 to 145 days in 209, while H2RA days covered decreased from 43 days to 38 days.** **H2RA step-down trials (i.e., H2RA post use) decreased from 8% in 2018 to 3% in 2019. Among members who discontinued a PPI and trialed an H2RA, 15% (2018) to 29% (2019) filled another PPI during the 56 day H2RA trial. The average length of H2RA trials slightly decreased from 33 days in 2018 to 30 days in 2019.** **Adverse events thought to correlate with long-term PPI use were not common and stayed fairly stable from 2018 to 2019. Adverse events associated with short-term PPI use also remained stable from 2018 to 2019 and were fairly uncommon: about 1% of members experienced C. Diff while 5% had CAP. Use of a PPI with a concomitant contraindicated medication increased slightly from 3% in 2018 to 3.5% in 2019. The average number of days with concomitant PPI and contraindicated drug was low but slightly increased from 3 days to 4 days.**

Question	Response
	About 62% of members had at least one ED visit in 2018, and 60% had an ED visit in 2019. Inpatient stays were less common, with 22% of members having at least one inpatient stay in 2018 and 20% of members having at least one inpatient stay in 2019. Mean count of ED visits and inpatient stays (2 and <1 per year, respectively) were low and remained relatively stable from 2018 to 2019. **The percentage of members each month with an H2RA step-down trial was generally decreasing before and after the interruption (i.e., the January 1, 2019 policy change). The slope of this line was -0.37 (i.e., a decrease of 0.37% each month) prior to the interruption. The change in slope from pre-to post-interruption was 0.11, indicating the slope post-interruption was not as steep as pre-interruption. The estimate of the pre-interruption slope can be added to the estimate of the change in slope from pre- to post-interruption to calculate the post-interruption slope as -0.26%. It is important to note the estimated change in slope was not statistically significant (p=0.35), while the slope prior to the interruption was significantly different from zero (p <0.001). The level change from just prior to the interruption compared to the month of the interruption was negative but not statistically significant (level change = -1.227%, p=0.09).** **Discussion:** **PPI therapy continues to be a highly prescribed mainstay therapy for symptoms of GERD. In this module, we isolated the GERD population and investigated the difference a policy change has made on their utilization and the utilization of the recommended step-down therapy of H2RAs. The overall utilization of PPIs slightly increased from the calendar year of 2018 vs the calendar year of 2019, by about 1400 members who filled at least 1 claim of a PPI. Approximately 18 thousand of these members had claims in both calendar year 2018 and 2019. 70% of members filling a PPI during this measurement period had a diagnosis of GERD. Approximately 30 thousand members**

Question	Response
	in each measurement year had the diagnosis of GERD. Twice daily dosing of a PPI decreased in 2019. This is likely resulting from added criteria for twice daily dosing requiring a step down from twice daily dosing to daily dosing. **Continuous use, defined as 60 days of continuous use with a gap no greater than 30 days, of a PPI occurred in 57% of the GERD population in 2018 and 66% of the GERD population in 2019. This measurement served as an identification step to determine what portion of the GERD population would have to trial an H2RA (in 2018) or would be a part of the hypothetical H2RA step-down group in 2019. Of the PPI continuous use GERD population, H2RA step-down was found to decrease by more than half from 7.8% in 2018 to 3.2% in 2019. The interrupted time series analysis shows H2RA step-down was generally decreasing from March 2018 through December 2019, with no significant change in the slope when compared from pre-to post-policy change.** **One possible explanation for the down-trend in H2RA trial is that after members have trialed, they may be meeting criteria to skip the trial as described in the criteria. This was the hypothesized result since the criteria directly impacted this measurement. 7.8% of the GERD population who did step-down seems like a low number as it was written in policy to step-down. Presumably, some of the members who were not required to step down in 2018 met one or more of the exceptions or had previously trialed a step-down and were allowed to continue without step-down for clinical reasons. They may have also had a diagnosis in addition to GERD that was exceptional.** **Another result supported the policy change impacting our measurement was the near doubling of the PPI post-start result, this showed that more members were continuing to PPI therapy after trial of step-down H2RA**

Question	Response
	therapy. All measured short-term and long-term adverse effects occurred at similar rates in 2018 compared to 2019. Long-term adverse effect change likely could not be accurately measured with this design, as the conditions in this group (i.e., hypomagnesemia, Vitamin B deficiency) take more time to reach a clinically relevant level. Case reports showing hypomagnesemia with continued use of PPI noted durations of PPI therapy for at least one year to be correlated with hypomagnesemia8. Vitamin B12 deficiency has been shown as an adverse effect of chronic use of greater than two years of a PPI, but notably, patients dispensed an H2RA were also found to have higher risk for vitamin B12 deficiency. **Individual-level results found similar, but slightly decreased counts of ED visits and hospitalizations. Also, the PPI utilizations trend upwards on all measured metrics including length of first continuous PPI use, average continuous PPI use, and days covered of PPI. H2RA average days covered and post continuous PPI days of continuous use both decreased. This is well in-line with what one would hypothesize the effect of the policy may be. With the increased use of PPI and more continuous use of PPIs, more drug-drug interactions were measured.** **Recommendations: First, maintain twice daily dosing criteria - a reduction of BID dosing is noted. Second, maintain softer step-down language - more PPIs with less H2RA step-down are being utilized; however, it is not affecting adverse events.** **Characterization of gabapentinoid use within Colorado Medicaid beneficiaries. (Delivered 9/30/2020)** **Objectives:** **Identify and describe members using gabapentin and pregabalin** **OUTCOMES: Gabapentin was used by approximately five times more members**

Question	Response
	than pregabalin, with about 3.5% of gabapentin users having an overlapping fill of pregabalin at some point. The mean age of members ranged from 44 years for gabapentin users to 47 years for pregabalin users. A small percentage of each drug group were pediatric members (age <18 years). More women filled these drugs than men, and nearly half of the members were White. Demographic characteristics of members with concomitant use were similar to those of gabapentin and pregabalin users and were similar across strata of varying durations of concomitant use Members were followed after their earliest gabapentin or pregabalin fill in the study period in order to measure drug and health service utilization. More than half of members had more than one year of follow-up after their first gabapentin or pregabalin fill, meaning their earliest fill of gabapentin or pregabalin was during the first year of the study. **From the list of on-label indications for gabapentin and pregabalin, the most common diagnosis among gabapentin users was partial seizure (0.8%) and among pregabalin users was fibromyalgia (19.7%). The next most common diagnosis among pregabalin users was diabetic peripheral neuropathy, followed by partial seizure and spinal neuropathic pain. Diagnoses associated with on-label indications for gabapentin occurred rarely. Among off-label uses for gabapentin and pregabalin, the most common diagnosis was anxiety disorder (34.5% and 38.0%, respectively). The next most common diagnosis for both gabapentin and pregabalin was chronic pain, followed by acute postoperative pain. Of note, certain indications or uses occur both on and off label as approved indications vary by specific drug formulations. The total percentage of on and off label indications is less than 100, reflecting some potential diagnoses not reflected in the analysis.**

Question	Response
	Describe gabapentin and pregabalin utilization and health service utilization **OUTCOMES: For the 58,256 members with at least one fill of gabapentin, the mean number of fills per member was 5.62 (standard deviation = 6.27, median = 3, range 1-82). Pregabalin was filled slightly more often; for the 11,011 members with at least one fill of pregabalin, the mean number of fills was 7.24 (standard deviation = 7.41, median = 4, range = 1-101). Supramaximal dosing was very rare for both gabapentin (n=181, 0.3%) and pregabalin (n=16, 0.1%).** **The mean refill tolerance for gabapentin and pregabalin was 91% and 95%, respectively. The majority of members had refill tolerance greater than/equal to 92%, with more members being in the highest tolerance category in the pregabalin group than the gabapentin group. These high refill tolerances indicate members are waiting to refill their gabapentin and pregabalin until they have used the majority of their current supply; this is also consistent with gabapentin and pregabalin refill tolerances observed within a national claims database (IQVIA). Note refill tolerance was very similar whether calculated at the claim level or member level. Demographic characteristics of those users who filled prescriptions early (refill tolerance <75%) were similar to characteristics observed in the overall cohort.** **Concomitant use of opioids was more common than concomitant use of benzodiazepines and muscle relaxants for both gabapentin and pregabalin. Over forty percent of gabapentin users had at least some concomitant use of an opioid, with 18% having at least 33% of their gabapentin use overlap with an opioid. More than half of pregabalin users (58%) had concomitant use of an opioid, with 35% having at least 33% of their pregabalin use overlap with an opioid. In general, pregabalin users were more likely to have concomitant use of opioids,**

Question	Response
	benzodiazepines, and muscle relaxants. Of note, 27% of pregabalin users had at least 33% of their pregabalin use overlap with a muscle relaxant. **Emergency department visits were common, with nearly three-quarters of gabapentin and pregabalin users having at least one all-cause ED visit. The mean number of all cause ED visits was 3-4 per member. Inpatient stays were less common (28%-30% of members). ED visits and inpatient stays due to poisonings were rare (less than 3% of members).** **Discussion:** **Gabapentin and pregabalin are commonly prescribed in the Health First Colorado population, with over400,000 claims paid for over 68,000 members in the study period of April 1, 2018 through March 31, 2020. Gabapentin was prescribed far more commonly than pregabalin, accounting for approximately 330,000 claims for 57,000 members. White and multiple races account for the majority of members receiving either drug. The vast majority of gabapentinoids are prescribed for adults, for which both agents are indicated (gabapentin is indicated for use down to 3 years of age for seizure disorder). There is a small amount of pediatric use, and concomitant use of both gabapentin and pregabalin.** **Receiving both gabapentin and pregabalin at the same time is a duplication of therapy and was hypothesized to be uncommonly found in claims data. The definition for concomitant use of these two drugs in this report was met if the member has >1 day overlap of days' supply for both claims. This is an easy target definition to meet for concomitant use; many of the members who met this definition may be transitioning from one drug to the other (most likely gabapentin to pregabalin).** **Diagnoses amongst the population of members receiving gabapentin or pregabalin**

Question	Response
	are varied. The list the DUR team used comes from clinically known off label indications, off-label indications described in Micromedex, and the FDA-approved indications with a primary focus on gabapentin. Using these indications, we found that nearly half of individuals receiving either gabapentin or pregabalin had an anxiety disorder. This does not mean these members were being prescribed either medication for an anxiety disorder, but rather that they had the diagnosis in medical claims history and were also receiving either medication. That said, gabapentin is commonly used for anxiety disorders and particularly those that do not respond to traditional therapies. Chronic pain and other pain disorders (many neuropathic) are also listed as commonly found diagnoses amongst the population receiving either medication. There are several off-label indications for which gabapentin or pregabalin may be prescribed, many of which are mental health disorders. Mental health disorders were not included due to lacking or controversial evidence without consensus support for use. **The mean days supplied used prior to refilling a medication is greater than 90% for both medications and both methods of analysis. The median for all groups in the refill tolerance analysis is greater than 95%, which enforces the claim that the vast majority of members are adherent to gabapentin or pregabalin. This analysis rests on the hypothesis that if the member was either non-adherent or exhibiting behaviors consistent with misuse, they would have fewer days elapsed prior to requesting a refill, indicating potential overuse or possible diversion.** **Widespread misuse or non-adherence is not found at the population level. Many of the lower % days-supplied that are used (i.e., <75% days-supplied used prior to refill request) may be resulting from titrating or tapering regimens. Gabapentin has a higher**

Question	Response
	refill rate at 85% or less of days-supplied used, somewhere in between 5-10%. This group may require more investigation to determine if this is a signal to non-adherence to their regimen or higher risk medication misuse. Policies applying controlled substance refill tolerance rules (i.e., >85% days-supplied used) to gabapentin would affect this population and could reduce the number of people filling early. We additionally found a moderate degree of other high-risk substances that are concomitantly prescribed including opioids, benzodiazepines, and skeletal muscle relaxants. All of these substances may increase CNS depression and may theoretically have a pharmacodynamic interaction with gabapentin or pregabalin. **Our data suggest providers may feel more comfortable prescribing pregabalin long-term than gabapentin as the rates of greater than/equal to 33% overlapping use are higher with all three higher risk substances compared to gabapentin. Although these numbers show a high degree of concomitant higher risk use, they should be added to the clinical context of each individual patient when considering overall risk. The retrospective letters could be used in this case to identify higher risk individuals and communicate risks to providers. A much smaller group of members had any ED visit for a poisoning code, which is being used as a proxy code for overdose for this analysis. A sub-group analysis could be used to correlate ED visits/hospital stays due to poisonings with refill tolerance. If at risk individuals are identified, the RDUR letter program or consult service may be used to provide an intervention with providers on behalf of members.** **Recommendations: First, consider further investigation of gabapentin group who refilled at <85% days-supplied used to determine if this group is at higher risk. Second, pending analysis in recommendation**

Question	Response
	one, consider policy applying controlled substance refill tolerance to gabapentin (greater than/equal to 85% days supplied used). Third, consider RDUR letters for concomitant use high risk scenarios. Fourth, consider subgroup analysis of early fill population and ED visits/hospital stays (with all-cause and poisoning). Fifth, if findings from above recommendations allow for interventions to be made, consider RDUR letter program. Sixth, given there are large amounts of off-label prescribing for these medications and minimal population level information suggesting large scale early refill misuse, consider avoiding prescription limitations by indication.

Section X – Managed Care Organizations (MCOs)

Question	Response
1. How many MCOs are enrolled in your state Medicaid program? If "Zero" or "None", please skip the rest of this section.	**2**
2. Is your pharmacy program included in the capitation rate (carved in)?	**Partial**
Please specify the drug categories that are carved out.	Certain outpatient hospital specialty drugs are carved out from Enhanced Ambulatory Patient Group (EAPG) payment. These drugs include Brineura, Spinraza, Kymriah, Yescarta, Danyelza, and Zolgensma.
3. If covered outpatient drugs are included in an MCO's covered benefit package, has the State updated their MCOs' contracts for compliance with Section 1004 of the SUPPORT for Patients and Communities Act?	**No, contracts are not updated**
Yes, contracts are updated to address each provision. Please specify effective date:	N/A
No, contracts are not updated, please explain.	Contractual updates related to rates will occur 07/01/21 followed by programmatic updates occurring by the end of August 2021.
a. Is the state complying with Federal law and monitoring MCO compliance on the SUPPORT for Patients and Communities Act provisions?	**Yes, state is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions**
Yes, state is complying with Federal law and monitoring MCO compliance on SUPPORT for Patients and Communities Act provisions. Please explain monitoring activities.	The State DUR Contact and other members of the State's Pharmacy Office team work directly with designated MCO DUR program pharmacist contacts (for each of the State's two MCOs) to coordinate DUR program activities and verify compliance with these provisions.
No, please explain.	N/A
4. Does the state set requirements for the MCO's pharmacy benefit (i.e. same PDL, same ProDUR/RetroDUR)?	**Yes**
a. If "Yes," please explain.	**Formulary Reviews**
b. Please briefly explain your policy.	**The State's policy is that MCO medication coverage and utilization limitations cannot be more stringent than current limitations in place for FFS. If a drug is carved out, then MCOs must follow the State's FFS PDL and associated prior authorization criteria.**

Question	Response
If "No," does your state plan to set standards in the future?	N/A
No, please explain.	N/A
5. Is the RetroDUR program operated by the state or by the MCOs or does your state use a combination of state interventions as well as individual MCO interventions?	**State uses a combination of state interventions as well as individual MCO interventions**
6. Indicate how the State oversees the FFS and MCO RetroDUR programs? Please explain oversight process.	**The State's two MCOs each have designated DUR program pharmacist contacts that collaborate with the State DUR Contact and other members of the State's Pharmacy Office team regarding MCO RetroDUR program activities. MCO DUR contractual obligations are also managed through coordinated efforts involving the MCO contract management team within the State's Health Programs Office.**
7. How does the state ensure MCO compliance with DUR requirements described in Section 1927(g) of the Act and 42 CFR part 456, subpart K?	**Designated DUR program pharmacist contacts for the State's two MCOs collaborate with the State DUR Contact and other members of the State's Pharmacy Office team regarding DUR activities. MCO DUR contractual obligations are also managed through coordinated efforts involving the MCO contract management team within the State's Health Programs Office. Verification and monitoring of MCO compliance with DUR requirements is conducted by direct communication from the State to the MCO DUR program pharmacist contacts.**
8. Did all of your managed care plans submit their DUR reports?	**Yes**
No, please explain.	N/A

Section XI – Executive Summary

Question	Response
Summary 6: Executive Summary Summary 6: Executive Summary should provide a brief overview of your program. It should describe 2020 highlights of the program, FFS initiatives, improvements, program oversight of managed care partners when applicable, and statewide (FFS and MCO) initiatives.	**The Health First Colorado (Colorado Medicaid) FFS DUR program is now in its eighth year of collaboration with the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Science (SSPPS). The DUR program continues to contract with a pain management specialist and a child and adolescent psychiatrist for teleconsultation services. In addition to the sub-contracted specialists, there are two clinical faculty members, an administrative faculty member, an analyst, and a pharmacy outcomes researcher involved in conducting DUR-related analyses and performing other DUR program activities. One clinical faculty member serves as a contracted clinical consultant and SSPPS liaison to the State, working directly with the State DUR Contact and other members of the Department's Pharmacy Office team.** **During the time period of the reporting fiscal year, Colorado's FFS DUR program added upon work performed previously related to the SUPPORT for Patients and Communities Act with development of a RetroDUR-generated provider educational outreach letter promoting use of naloxone in high-risk patients and a pharmacy claims systems edit for concomitant use of opioid and MAT medications. Collaborative work has continued with MCO DUR programs to ensure compliance with SUPPORT Act DUR provisions. In response to the COVID-19 pandemic, changes were made to pharmacy policies and systems edits for early refill, mail-order prescriptions, and prior authorization requirements for cough and cold medications. The DUR team also conducted an analysis to identify trends or potential changes in opioid utilization during the pandemic and with respect to issuance of stay-at-home orders. Additional DUR and policy-related medication management changes made during the reporting fiscal year included incorporation of patient-specific clinical lab data into pharmacy claims systems edits, implementation of a claims**

Question	Response
	systems edit for automated PA approval of oral MAT medications, and expansion of vaccine coverage to include pharmacist-administered influenza vaccines. **DUR Board meeting agendas have continued to be very full as additional drug classes have been added to the State's FFS pharmacy PDL. New PDL classes added during FFY 2020 included ophthalmic anti-inflammatory agents, self-administered glucagon agents, lithium products, and hemorrhoidal and related anorectal agents. The DUR Board continues to have high quality discussion leading to high quality recommendations made to the Department. Though changes were made to accommodate for the need to conduct public DUR Board meetings virtually, meetings continue to occur at a quarterly frequency and last approximately 4-5 hours.**