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VALUE IN HEALTH CARE

Data Release Application

Limited and Identifiable Extracts

Navigation

Data Release Application

Custom De-Identified Extract

Client Application Revision History

The following reflects the history of changes made to this document during the application process prior to project production. Once in production, any further changes to the application may result in additional cost and production delays.

To be completed by CIVHC staff			
Date	New Version Number	Description of Change(s)	CIVHC Change Author (full name, complete title)
6/23/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager
8/4/2024	V.02	Converted from custom report to limited/identifiable extract application.	Lucía Sanders, Key Account Manager
8/19/2024	V.03	Added detail to research aims. Expanded dates to 2019-most recent data. Added financial data elements.	Lucía Sanders, Key Account Manager
8/22/2024	V.04	Replace Charge Amount with Allowed Amount. Added Member Liability Amount and Member Eligibility Dates.	Lucía Sanders, Key Account Manager
9/18/2024	V.05	Removed request for member name as DOB as it is no longer needed.	Lucía Sanders, Key Account Manager
	V.06		
	V.07		
	V.08		
	V.09		
	V.10		

Data Release Application

Custom De-Identified Extract

Data Requestor Details

General Project Details

Project Title:	Outcomes After Initiation of IM-naltrexone vs. Oral naltrexone at Hospital Discharge
Application Start Date:	6/14/2024
Requested Project Delivery Date:	12/31/2024
Client Organization (legal name):	University of Colorado, Anschutz Medical Campus; Denver Health
Client Organization Address:	CU Anschutz Leprino Building 12401 East 17th Avenue 4th Floor Aurora, CO 80045
To be completed by CIVHC staff	
CIVHC Contact (full name, complete title):	Lucía Sanders, Key Account Manager
Project Number:	24.59
Condensed Project Title:	Outcomes After Naltrexone

Project Contacts

Project Contact Name:	Susan Calcaterra
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Data Release Application

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Project Schedule and Purpose

Proposed Project Start Date[1]:	10/31/2024
Anticipated Project End Date:	9/1/2025
Proposed Publication or Release Date:	9/1/2025

1. Detail the specific research question(s) you are trying to answer or problem(s) you are trying to solve with this data request. Please list and number the individual questions.

To investigate the association between receipt of in-hospital IM-naltrexone injection vs. receipt of a discharge prescription of oral naltrexone at an index hospitalization on subseqent 90-day acute care encounters.

Or stated another way: Among hospitalized patients with alcohol use disorder, is the initation of in-hosptial IM-naltrexone for alcohol use disorder vs. the initiation of oral naltrexone for alcohol use disorder at hospital discharge associated with future 90-day acute care encounters?

Primary outcome: a composite of all cause emergency department encounters + all cause hospitalizations in the 90 days following an index hospitalization among patients who received in-hospital IM naltrexone vs. patients who received a discharge prescription for oral naltrexone.

Individual research questions:

i. Secondary outcome 1a: a composite of 30-day all-cause emergency department encounters + 30-day all-cause hospitalizations between patients who received in-hospital IM naltrexone vs. patients who received a discharge prescription for oral naltrexone

ii. Secondary outcome 1b. a composite of 90-day alcohol-related emergency department encounters + 90-day alcohol-related hospitalizations between patients who received in-hospital IM naltrexone vs. patients who received a discharge prescription for oral naltrexone

iii. Secondary outcome 1c. a composite of 30-alcohol-related emergency department encounters + 30-day alcohol-related hospitalizations between patients who received IM naltrexone vs. patients who received a discharge prescription for oral naltrexone

In addition to the primary study aims, our a priori subgroup analysis will include the following:

[1] After all required documents have been signed, typical production time is 30-60 days for a Limited or Identifiable Extract. Anticipate a longer production period for projects including a Finder File or creation of a Member Match File.

i. Clinically relevant subgroups: Do the outcomes described above differ by: the presence of chronic pain, the presence of other substance use disorders, older vs younger age groups, race and ethnicity, sex, insurance status/type (including benefit design), and housing status?

ii. Unique treatment contexts: Do differences in outcomes described above differ based on the presence of additional medications for alcohol use disorder at discharge, addiction medicine consultation during hospitalization, and length of hospitalization?

We plan to identify other relavent subgroups and treatment contexts during initial exploratory data anlaysis that could be ascertained from available care utilization data. This would serve the purpose of optimizing and personalizing clinical care for highly vulnerable Coloradans struggling with alcohol use disorder, a disease that impacts economic productivity, families, public safety, and health systems.

2. Describe your methodology or how you will be using data from the Colorado All Payer Claims Database (CO APCD) to answer your research questions.

We will send CIVHC two finder files that include patient names and DOB (or whatever identifiers are most useful for CIVHC) for (a) patients that were hopitalized at the University of Colorado Hospital and (b) patients that were hospitalized at Denver Health Hospital with an ICD code for alcohol use/abuse/dependence (F10.1X, F10.2X, F10.9X) excluding patients with an ICD code signifying “in remission”, ICD codes F10.11, F10.21, F10.91.

We are requesting from CIVHC all pharmacy claims data, inpatient claims data, outpatient claims data, and professional facility claims data from years 2019 to 2023.

Claims data will be used to build our cohorts and propensity match on key characteristics we identify using data warehouse data from Univeristy of Colorado and Denver Health (i.e., patients will be excluded if they have an opioid prescription 30 day prior to their index hospitalization, we will match our patients on previous acute care and outpatient encounters, etc.).

We will combine CIVHC data, Univeristy of Colorado data, and Denver Health data to create a propensity matched cohort of patients who were hospitalized and received either an injection of IM naltrexone during an index hospitalization or a discharge prescription for oral naltrexone within 72 hours of an index hospitalization. Outcomes are to examine for an association between medication receipt and subsequent 90-day acute care encounter.

Additional secondary analyses of clinical subgroups and scenarios will occur after the primary analysis to maximize the alcohol treatment knowledge to be gained among this high risk sample.

3. Explain how this project will benefit Colorado and its residents.[2]

> Unhealthy alcohol use is a leading cause of morbidity and mortality among Coloradans. Hospitalizations related to complications from unhealthy alcohol use are rising, especially following the COVID 19 pandemic. Examples of medical complications related to excessive alcohol use include liver failure, pancreatitis, and death. Medications for alcohol use disorder (AUD) are highly effective to reduce alcohol use. While oral medications for AUD, including naltrexone, are associated with a reduction unhealthy alcohol use, medication effectiveness is dependent on daily use. In reality, many people struggle to take a daily medication. Intramusular (IM) naltrexone also reduces unhealthy alcohol use, similar to oral naltrexone. IM naltrexone is given as a once monthly depot injection and its effect lasts for 30 days. However, IM naltrexone is more costly than oral naltrexone and, because of this, it is not typically offered, or administered, in the hospital setting. Whether or not IM naltrexone reduces acute care hospitalization compared to oral naltrexone is unknown. Denver Health and Univeristy of Colorado Hospital partnered with Alkermes, the drug manufacturers of IM naltrexone, to offer it freely to hospitalized patients with severe AUD. This unique programs presents an opportunity to study otucomes related to in-hosptial administration of IM naltrexone vs. oral naltrexone. If the data demonstrate that IM naltrexone reduces acute care utilization vs. oral naltrexone, thereby reducing total health care costs, then we can make an argument to insurers to cover its administration in the hospital setting as a cost saving intervertion that could benefit the people of Colorado.
>
> Further, analyses of clinical subgroups and treatment contexts among this population will help tailor treatment, ultimately helping Coloradans with alcohol use disorder get the right care in the right siutations and reducing costs to all Coloradans who subsidize health care via taxes.

4. Describe how your project will improve health care quality, increase health care value, or improve health outcomes for Colorado residents.[2]

> If IM-naltrexone is associated with a reduction in acute care utilization compared to oral naltrexone, in-hospital administration to high risk, hospitalized patients would increase health care value by reducing total health care costs and by reducing the negative health consequences related to heavy alcohol use.
>
> And tailoring care based on specific subgroups and treatment contexts will help ensure Coloradans with alcohol use disorder get the right care in the right situations, better aligning resources with needs and optimizing health care value.

[2] It is a statutory requirement for all non-public releases of CO APCD data to benefit Colorado or its residents. Contributions to generalizable knowledge alone are not sufficient to satisfy this requirement.

5. Health equity is defined as the state in which everyone has a fair and just opportunity to attain their highest level of health. Explain how your project addresses health equity.

Currently, IM-naltrexone is only offered in the outpatient setting due to its cost. There are patients with severe AUD who are repeatedly hospitalized due to an inability to stop or cut back their alcohol use. Many of these patients are in the throes of addiction – they lack housing, transportation, social support, and they are at high risk of death. These patients should receive the benefit of a long-acting injectable medication to reduce their alcohol use in any treatment setting, inpatient or outpatient. This study will examine if there is benefit to administering IM naltrexone in the hospital to a high risk patient population. If IM-naltrexone is associated with a reduction in acute care utilization compared to oral naltrexone, the we can make a strong argument to insurers to offer this medication in the hospital setting to reduce health care costs and improve the health of all patients, in any treatment setting. Our planned subgroup analysis will evaluate outcomes by race, ethnicity, and sex to understand how outcomes differ among minoritized populations.

6. Describe any publication you plan to develop based on your use of CO APCD data, its intended audience, and whether it will be made publicly available.

We anticipate that these data will be used in at least two manuscripts that will be submitted for peer review and publication in general internal medicine-focused journals. These articles will be made publicly available after a journal-initiated embargo period. We do not have the funds to pay for publishing fees for open access. We will also present the findings at scientific meetings (addiction-focused and hospital-medicine focused). Immediately upon publication acceptance of any resulting manuscript, we will contact University of Colorado and Denver Health's media relations for a press release. We are very open and would like to partner with CIVHC to create other citizen facing flyer or publication that is of interest and could reach a broad audience.

Data Matching and Linkage

Finder File

A Finder File is a file you submit to CIVHC with information about a pre-selected cohort for matching to CO APCD data. Ask your CIVHC Contact for more information about this process and requirements for Finder File submission.

Will you provide CIVHC with a Finder File as part of this project?

- ☐ No
- ☒ Yes

Member Match File

A Member Match File is a file that CIVHC creates on your behalf to send to a registry or other outside entity to create a crosswalk connecting data from the CO APCD to the other entity's data.

Does this project require the creation of a Member Match File?

- ☒ No
- ☐ Yes. Consult with your CIVHC Contact about completing a separate Data Element Selection Form specifying the data elements that should be used to create the Member Match File.

  Answer the following:

Who will receive the Member Match File?

Control Group

A Control Group is a group of individuals who can be used to compare against the cohort identified in the Finder File.

Will you need to create a Control Group as part of this project?

- ☒ No
- ☐ Yes. Consult with your CIVHC Contact about completing a separate Control Group Data Element Selection Form specifying the data elements that should be used to define the Control Group.

Linkage

Data Linkage is a method of joining data from different sources together to create a new data set.

Will the CO APCD data be linked to another data source?

☐ No
☒ Yes. Answer the following:

What is/are the other data source/s?
Patient data from the electronic medical records at UCHealth Patient data from the electronic medical records at Denver Health
Who will perform the data linkage?
Eric Grimm at University of Colorado Ryan Loh at Denver Health
What identifying data elements will be used to perform the data linkage?
Medical Record Number
What non-CO APCD data elements will appear in the new linked file?
Hospital admission medication reconciliation Discharge medication reconciliation In hospital receipt of IM naltrexone (not billed to insurance because it is part of a free drug trial manufacturer's program)

Data Inclusion Criteria

Make selections in the following sections based on what data you want to have included in this extract. If you will be creating a Control Group, complete this section for your study population and not the Control Group.

Protected Health Information (PHI)

Indicate which Protected Health Information data elements you require for your project purpose:

Available for Limited and Identifiable extracts:		
☐ Member 5-Digit Zip Code	☐ Member County	☐ Member City
☒ Member Dates of Service	☒ Member Eligibility Dates	☐ Employer Name
☐ Member Census Tract	☐ Member Census Block	☐ Member Census Block Group
Available for Identifiable extracts only (see also Identifiable Data Use Approval):		
☐ Member Name	☐ Member Date of Birth (if requesting more than year only)	
☐ Member Street Address	☐ Member Latitude and Longitude	
☐ Employer Tax ID		
Provide detailed justification for the inclusion of all PHI data selected above, and explain how its inclusion meets the Minimum Necessary Requirement.[3]		
Dates of service are required to identify 30-day and 90-day ED visits and hospitalizations. Eligibility dates are needed to determine start and end dates of insurance coverage, whether coverage was in place at time of service, as well as insurance churn.		

[3] Limited and Identifiable extracts must adhere to the Minimum Necessary Requirement under the HIPAA Privacy Rule; only that data required to answer the project purpose can be included in the request.

Line(s) of Business

- ☒ Commercial Payers
- ☒ Health First Colorado (Colorado's Medicaid and CHP+ programs)[4]
- ☒ Medicare Advantage
- ☒ Medicare Fee for Service (FFS)[5]

Year(s) of Data

☐ 2012	☐ 2013	☐ 2014	☐ 2015	☐ 2016	☐ 2017
☐ 2018	☒ 2019	☒ 2020	☒ 2021	☒ 2022	☒ 2023[6]

Claim Type(s)

☒ Inpatient Facility	☒ Outpatient Facility	☒ Professional
☒ Pharmacy	☐ Dental	

Financial Detail by Line Item

☐ Charged Amount	☒ Allowed Amount	☐ Plan Paid Amount
☐ Plan Pre-Paid Amount	☒ Member Copay	☒ Member Deductible
☒ Member Coinsurance	☒ Total Member Liability	

[4] Medicaid-only data requests must be approved by the Colorado Department of Health Care Policy and Financing.
[5] Medicare FFS data are not available for all requests and must go through a separate approval process.
[6] This year's data is not fully adjudicated.

Filter Criteria – Services, Providers, Facilities

If you need data for specific services, providers and/or facilities, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

ICD Diagnosis Code(s):
Procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):
Drug(s) (list pharmacy NDC and/or HCPCS codes):
Facility Type(s):
Facilities (list NPIs and/or Pharmacy IDs):
Facilities within these geographical areas (list county, zip code, Census Tract, etc.):
Provider Type(s):
Provider(s) (list NPIs):
Providers within these geographical areas (list county, zip code, Census Tract, etc.):
Specific payers (minimum of five):

Other claim specification:

Filter Criteria – Members/Patients

If you need data for specific member/patient groups, specify that filter criteria below (ask your CIVHC Contact about including an additional file with this application for large code lists):

Ages:		
All claims during time period for finder file population		
☐ At the time of service	☐ At year end	☐ By another anchor date: *Specify here*
With these ICD Diagnosis Code(s):		
Who have had the following procedure(s) (list CPT, HCPCS, DRG, ICD, and/or CDT codes):		
Within these geographical areas (list county, zip code, Census Tract, etc.):		

Value-Add Data Elements

- ☐ Medicare Severity Diagnosis Related Group Codes (MS-DRGs)
- ☐ 3M All Patient Refined Diagnosis Related Group Codes (3M APR DRGs)
- ☐ Medicare Repricer (available at the claim line level)
- ☐ Fields from the American Community Survey (available at the Census Tract level):

Specify here

Additional Documentation

Data Element Selection Form (DESF)

The Data Release Application must be accompanied by a completed Data Element Selection Form. Ask your CIVHC Contact for more information about completing this form.

☒ By checking this box, the Client Organization confirms that the Data Element Selection Form has been completed.

☐ If applicable, by checking this box the Client Organization confirms that a separate Member Match File Data Element Selection Form has been completed.

☐ If applicable, by checking this box the Client Organization confirms that a separate Control Group Data Element Selection Form has been completed.

Identifiable Data Use Approval

If you are requesting Identifiable information, approval from an Institutional Review Board (IRB) or a Privacy Board is required before such data can be released.

☐ Not applicable; the Client Organization is requesting a Limited Extract.

Approval Type

☒ IRB Approval

☐ Privacy Board Approval

Approval Type

☐ Approval request not yet submitted.
Anticipated submission date:

☐ Approval request submitted and under review.
Anticipated project approval date:

☒ Approval already received.

Approval Documentation

☐ By checking this box, the Client Organization confirms that the IRB or Privacy Board **application and approval documents** have been provided to CIVHC.

Data Management Plan

An organization requesting CO APCD data must submit an organizational Data Management Plan to CIVHC outlining the organization's data security and data management policies and procedures to safeguard the data. This Data Management Plan must be approved by CIVHC prior to any data release.

Date Submitted to CIVHC:	
Date Approved by CIVHC:	

Client Acknowledgements and Signatures

Change Agent Index

CIVHC can publicly share the Client Organization's name in its Change Agent Index?

☒ Yes
☐ No

Report or Product Distribution

If your project results in the production of a report for public distribution in any format (print, electronic, lecture, slides, etc.), including peer-reviewed publication, it must be submitted to CIVHC for review prior to public release. CIVHC will assess compliance with CMS Cell Size Suppression Policy, risk of inferential identification, CIVHC and CO APCD citations, and consistency with the purpose and methodology described in this Data Release Application. CIVHC will not assess the accuracy of the study results or attempt to recreate results.

This requirement is further defined in the Data Use Agreement. Failure to pursue and obtain CIVHC approval prior to publication will be a violation of the Data Use Agreement and may put the organization's future access to data from the CO APCD at risk.

☒ By checking this box, the Client Organization acknowledges this requirement.

Data Destruction Period

All data must be destroyed within 30 days of the project end date. If your project end date changes from this application, please reach out to your CIVHC Contact for a project extension request form.

☒ By checking this box, the Client Organization acknowledges that CIVHC's Data Destruction Certificate[7] must be completed and returned to DataCompliance@CIVHC.org by 10/1/2025 based on the Anticipated Project End Date.

Data Users

List any individuals that will be working with the data. The Data Use Agreement must be updated through your CIVHC Contact every time individuals are granted access to the data during the course of the project.

Full Name	Title/Role	Organization
Susan Calcaterra	Associate Professor, primary contact	University of Colorado Anschutz Medical Campus
Eric Grimm	Data analyst	University of Colorado Anschutz Medical Campus
Angela Keniston	Statistician	University of Colorado Anschutz Medical Campus
Jarratt Pytel	Co investigator	Denver Health Medical Center
Dale Terasaki	Co investigator	Denver Health Medical Center
Ryan Loh	Statistician	Denver Health Medical Center
Alex Tillman	Data analyst	Denver Health Medical Center
Paul Christine	Co investigator	Denver Health Medical Center

[7] Available on the Data Release Application and Documents page of CIVHC's website under *Privacy, Security, and Regulatory Information*.

Data Release Application Version Approvals

The Client Organization has reviewed and confirms that the final version number of the Data Release Application reflected below correctly represents the project objectives.

Version	Checkpoint
V.04	Presented at CIVHC Application Review
V.05	Presented to the Data Release Review Committee (DRRC)
V.00	Final version approved for production

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

Data Element Selection Form Version Approvals

The Client Organization has reviewed and confirms that the final version number of the Data Element Selection Form reflected below correctly represents the data specifications needed to meet the project objectives.

Version	Checkpoint
V.03	Presented at CIVHC Application Review
V.04	Presented to the Data Release Review Committee (DRRC)
V.00	Final version approved for production

CIVHC Sign-Off		Receiving Organization Sign-Off	
Signature:		Signature:	
Name:		Name:	
Title:		Title:	
Date:		Date:	