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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)
12/31/2024	V.01	Initial version drafted with client.	Lucía Sanders, Key Account Manager
1/6/2025	V.02	Updated project start and end dates.	Lucía Sanders, Key Account Manager
1/15/2025	V.03	Clarified research aims, methodology, and need for claim paid dates.	Lucía Sanders, Key Account Manager
1/27/2025	V.04	Expanded language around temporal trends. Added detail regarding population size.	Lucía Sanders, Key Account Manager
	V.05		
	V.06		
	V.07		
	V.08		
	V.09		
	V.10		

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Data Requestor Details

General Project Details

Project Title:	Healthcare Resource Utilization in Patients with Demyleniating Neurological Diseases: Multiple Sclerosis and Neuromyelitis Optica Spectrum Disorder (NMOSD)
Application Start Date:	12/31/2024
Requested Project Delivery Date:	4/30/2025
Client Organization (legal name):	University of Colorado School of Medicine
Client Organization Address:	12631 East 17th Ave. Mail Stop B185 Aurora, CO 80045
CIVHC can publicly share the Client Organization's name in its Change Agent Index.	☒ Yes ☐ No
To be completed by CIVHC staff	
CIVHC Contact (full name, complete title):	Lucía Sanders, Key Account Manager
Project Number:	25.16
Condensed Project Title:	Multiple Sclerosis NMOSD

Project Contacts

Project Contact Name:	**Kavita V Nair, PhD**
Title:	Professor of Neurology and Pharmacy
Email:	Kavita.Nair@cuanschutz.edu
Phone Number:	720-277-5855

Analytic Contact Name:	**Eric Gutierrez, MPH**
Title:	Sr. Professional Research Assistant
Email:	ERIC.GUTIERREZ@CUANSCHUTZ.EDU
Phone Number:	520-401-6881
Invoice Contact Name:	**Neurology Billing**
Title:	
Email:	neurologybilling@ucdenver.edu
Phone Number:	303-724-0350
Data Release Fee Signatory:	**Chrissy Alexander**
Title:	Senior Purchasing Agent
Email:	chrissy.alexander@cu.edu
Phone Number:	303-764-3472
Data Use Agreement Signatory:	**Chrissy Alexander**
Title:	Senior Purchasing Agent
Email:	chrissy.alexander@cu.edu
Phone Number:	303-764-3472

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Project Schedule and Purpose

Proposed Project Start Date[1]:	4/30/2025
Anticipated Project End Date:	4/30/2030
Proposed Publication or Release Date:	3/31/2026

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.

> This project aims to better characterize utilization of healthcare resources for patients living with two related demyelinating diseases, multiple sclerosis (MS) and neuromyelitis optica spectrum disorder (NMOSD). MS is a leading cause of disability in young adults and NMOSD, while much less common, can lead to severe injury after a single inflammatory attack. In recent years, multiple therapies have been developed that can be effective at reducing risk of inflammatory injury. However, there is limited data on how patients living with these conditions access healthcare and how different therapies impact healthcare utilization and overall clinical outcomes
>
> We will identify patients with NMOSD followed in the academic UCHealth system and patients living with MS followed at UCHealth and at Denver Health. For this larger population of patients living with MS split across two unique sites of care, we will be able to better parse out the impact of social determinants of health and how they influence access to MS care at two different sites of care. We will retrospectively evaluate outcomes including hospitalizations, emergency room visits, medication use, and other utilization patterns.
>
> The first therapies for NMOSD were approved in 2019 and the first widely-used high-efficacy therapy for MS was approved in 2017. In order to understand temporal trends of utilization and management of these diseases in context of this evolving treatment landscape we will look back to the 2012 advent of UCHealth's integrated Epic electronic medical record.
>
> *Individual research questions:*
>
>   i.   What is the pattern of healthcare resource utilization in patients with demyelinating disease in Colorado?
>
>   ii.   What is the annual cost of treating patients with demyelinating disease in Colorado?
>
>   iii.   What are the drug treatment options most often used to manage demyelinating disease in Colorado? Does access to drug treatment options vary by site of care? Do

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[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.

> MS patients treated at Denver Health receive access to highly efficacious MS drug treatments similar to those treated at University of Colorado Hospital.
>
> iv.   Does delayed/misdiagnosis of demylienating disease occur and what healthcare resources are consumed unnecessarily in reaching the correct diagnosis?
>
> v.   How often are patients with demyelinating disease hospitalizatized or present in the emergency room due to relapses as a result of uncontrolled or poory managed disease? What demographic, clinical and geographic factors influence this outcome?
>
> vi.   Does urban vs rural areas impact the pattern of resource utlilization in patients with demylienating disease?
>
> vii.   What is the out of pocket cost burden for patients in their diagnostic oddessy with demylienating disease?

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 use the data obtained to quantify hospitalizations, emergency room visits, outpatient visits, laboratory and radiology services, and medication use (disease-modifying therapies, antbiotics, and symptomatic therapies) to evaluate all cause and MS and NMOSD specific healthcare resource utilization and costs. In addition, patient out of pocket costs incurred while obtaining the demylelinating diagnosis will also be estimated.

We will use our group of identified NMOSD patients whose journey we will examine using the CO APCD. NMOSD patients are often with MS and other inflammatory conditions. Previous studies have posited a misdiagnosis rate as high as 40%. Using the established date of NMOSD diagnoses for our University of Colorado sample, we will conduct a review of the look period in the CO-APCD to evaluate if a prior diagnosis of MS or other inflammatory diagnosis as made and then determine the length of time between an incorrect diagnosis and the appropriate established NMOSD diagnosis. We will also evaluate time from first neurology clinic visit to established NMOSD diagnosis.

Costs will be standardized to real dollars to remove the effect of inflation. Regression or generalized regression models will adjust for covariates to include age, sex, disease duration, and exposure time, number of unique disease modifying agents used.

Clinical data is available in UCHealth Epic from 2012-2019. Rituximab was heavily utilized as first-line therapy for NMOSD at UCH which is an ultra rare disease. In 2019 there was a shift to FDA-approved therapies. In order to capture sufficient follow-up time on rituximab treatment for NMOSD, our plan is to capture data from 2012-2019 as an epoch to adequately gather cases with multiple clinical follow-up encounters on rituximab given the rarity of NMOSD. We will also capture data form 2019-2024 predominantly to evaluate longitudinally healthcare utilization patterns and real world treatment costs with FDA-approved therapies.

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

Better understanding how patients living with MS and NMOSD interact with the healthcare system can help improve treatment outcomes and may allow for targeted interventions to reduce risk of disability accumulation. Examining differences in utilization, time to diagnosis and factors affecting access to care between two sites of care, Denver Health and University of Colorado Hospital will provide opportunities for intervention such that dispatities in care may be reduced.

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[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.

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

> Improved understanding of how patients living with MS and NMOSD are treated may allow for improved models of care across two prominent sites of care that can impact outcomes and value.

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.

> This projects aims to improve health equity by better understanding treatment outcomes and associated barriers and differences in healthcare utilization for patients with different demyelinating diseases. Data collected can be used to identify disparities in care among differing patient demographics with MS and NMOSD and between sites of care (Denver Health versus University of Colorado Hospital).

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 plan to disseminate findings from our study at both national and international neurology conferences (such as the American Academy of Neurology Annual Meeting) and in written format in peer-reviewed journals with open access. All publicly available data will be aggregated and without any personal identifiers or other protected health information.

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VALUE IN HEALTH CARE

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 CIVHC 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.

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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?
Health Data Compass
Who will perform the data linkage?
Eric Engebretson (Analyst, CU Research Team)
What identifying data elements will be used to perform the data linkage?
CO APCD Member Composite ID and Health Data Compass MRN (via crosswalk provided by CIVHC)
What non-CO APCD data elements will appear in the new linked file?
Clinical data for MS and/or NMOSD diagnosis: Neurology encounters, diagnostic testing, treatments

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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	☒ Claim Paid 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	
Provide detailed justification for the inclusion of all PHI data selected above, and explain how its inclusion meets the Minimum Necessary Requirement.[3]		
Zip codes, counties and cities are being requested to understand if living in urban, rural or frontier impacts the resource patterns and utilization of patients with MS or NMOSD. This may aid in identifying disparities of care with regards to proximity to treatment and other resources. Dates of service and eligibility dates are being requested to explore the timeline of patients' access to care along their diagnostic journey of MS or NMOSD. This, in addition to claim paid dates, can help understand the costs incurred before and after a patient's diagnosis.		

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[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.

> Utilization of healthcare resources encompasses claims approved by insurance providers which we can't fully understand without a paid date being available. Claim paid dates allow us to be more specific in our timeline of interest such as examine when newer disease modifying medications were introduced allow for the application of specific inclusion and exclusion criteria, for example how much time lapsed between a patient suspect of NMOSD and receiving a confirmatory lab test for AQP4 test for antibodies for NMOSD. Another example, would be to understand if a MS/NMOSD patient's claim is taking a significantly longer time to be paid, claim paid dates would allow us to track that as well since delays of paying out a claim contribute to additional financial burdens and delayed care.

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
☒ 2024[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

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[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 incomplete and not fully adjudicated. Consult with your CIVHC Contact to find out what data is available at the time of your request.

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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 patients in finder file		
☐ 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

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 5/30/2030 based on the Anticipated Project End Date.

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

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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
Kavita Nair	Principal Investigator	University of Colorado Anschutz Medical Campus
Andrew Wolf	Co-Investigator	University of Colorado Anschutz Medical Campus
Jeffrey Benett	Co-Investigator	University of Colorado Anschutz Medical Campus
Eric Gutierrez	Lead Data Analyst	University of Colorado Anschutz Medical Campus
Stefan Sillau	Statistician	University of Colorado Anschutz Medical Campus
Eric Engebretson	Project Manager	University of Colorado Anschutz Medical Campus
Lexer Sanchez Duque	Project Coordinator	University of Colorado Anschutz Medical Campus

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.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:	Lucia Sanders	Name:	Kavita V. Nair
Title:	Key Account Manager	Title:	Principal Investigator
Date:		Date:	

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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.02	Presented at CIVHC Application Review
V.02	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:	Lucía Sanders	Name:	Kavita V. Nair
Title:	Key Account Manager	Title:	Principal Investigator
Date:		Date:	