New Medicaid Coverage Requirement related to Clinical Trials State Plan Amendment
effective January 1, 2022

On or before March 31, 2022, the Montana Department of Public Health and Human Services
(DPHHS) is submitting a State Plan Amendment (SPA), effective January 1, 2022, to meet new
requirements to cover routine patient costs related to Medicaid members’ participation in
qualifying clinical trials.

The Consolidated Appropriations Act (CAA) adds a new mandatory 1905(a)(30) benefit that
covers services in connection to qualifying clinical trials, effective January 1, 2022. The aim of
this policy is to allow Medicaid members to participate in these qualifying clinical trials. States
will need to submit a new coverage SPA to effectuate this new coverage requirement, effective
with respect to items and services furnished on or after January 1, 2022, unless the exception for
state legislation described above applies. Additionally, states will need to submit a
reimbursement SPA to describe payment methodologies that will be used to pay service
providers.

States do not need to add any new services to their state plans or waivers. Routine patient costs
do not include any investigational item or service that is the subject of the trial and not currently
covered under a state plan or waiver.

Because Montana Medicaid already covers routine patient care for patients participating in a
clinical trial, the amendment is not expected to have an impact on Montana Medicaid
expenditures.

We invite your public comments and questions postmarked through January 31, 2022. You
may direct comments to Mary Eve Kulawik, Medicaid State Plan Amendment and Waiver
Coordinator, at (406) 444-2584 or mkulawik@mt.gov; or Director’s Office, PO Box 4210,
Helena MT 59604-4210.