

Marketplace National Regional Benefit Interpretation Document

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| Benefit Name | CLINICAL TRIALS |
| Applicable State | California, Florida, Idaho, Illinois, Kentucky, Michigan, Mississippi, New Mexico, Ohio, South Carolina, Texas, Utah, Washington, Wisconsin |
| Benefit Definition | <p>This policy addresses state mandates pertaining to clinical trials.</p> <p>Covered benefits are listed in three (3) Sections - A, B and C. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations and exclusions as stated in the member’s Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member’s EOC/SOB, the member’s EOC/SOB provision will govern.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>A. FEDERAL/STATE MANDATED REGULATIONS</p> </div> <p>Note: The most current federal/state mandated regulations for each state can be found in the links below.</p> <p>FEDERAL: PHS ACT SEC. 2709. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS</p> <p>CALIFORNIA: CA Health & Safety Code; Division 2-Licensing Provisions; Chapter 2.2-Health Care Services Plans; Article 5-Standards: CA H&S Code §1370.6-Cancer Clinical Trial Coverage</p> <p style="margin-left: 40px;">CA Health & Safety Code 1367.45</p> <p>ILLINOIS: P.A. 97-0091; 215 ILCS 5/364.01(c): Qualified clinical cancer trials</p> <p>KENTUCKY: Ky. Rev. State. § 304.17A-136: Coverage for cancer clinical trials.</p> <p>OHIO:</p> |

[Ohio Rev. Code § 1751.01\(A\)\(1\)\(i\)](#): Basic health care services: Routine patient care for patients enrolled in an eligible cancer clinical trial pursuant to section [3923.80](#) of the Revised Code (Denial of coverage to cancer clinical trial participant)

TEXAS:

CHAPTER 1379. COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR ENROLLEES PARTICIPATING IN CERTAIN CLINICAL TRIALS; SUBCHAPTER B.; COVERAGE FOR ROUTINE PATIENT CARE COSTS;: Coverage for Routine Patient Care Costs-Clinical Trials (**SB 39, Applies to policies issued or renewed on or after 1/1/10**)

[Sec. 1379.051; Routine Patient Care Costs](#)

[Sec. 1379.052; Coverage Required](#)

[Sec. 1379.053; Research Institution](#)

[Sec. 1379.054; Limitations on Coverage](#)

[Sec. 1379.055; Deductible, Coinsurance, and Copayment Requirements](#)

[Sec. 1379.056: Cancellation or Nonrenewal Prohibited](#)

[42 USC § 300gg-8](#): Coverage for individuals participating in approved clinical trials

WASHINGTON:

[Clinical Trials \(WAC 284-43-5420\)](#)

WISCONSIN:

Coverage of Certain Health Care Costs in Cancer Clinical Trials

[632.87 \(1\)](#): Restrictions on health care services

[632.87 \(6\)](#): Clinical Trials

B. STATE MARKET PLAN ENHANCEMENTS

None

C. COVERED BENEFITS

IMPORTANT NOTE: Covered benefits are listed in Sections A, B and C. Always refer to Sections A and B for additional covered benefits not listed in this Section.

Refer to the member's Evidence of Coverage (EOC) and Schedule of Benefits (SOB) to determine coverage eligibility.

APPROVED CLINICAL TRIALS

CALIFORNIA, FLORIDA, MICHIGAN, MISSISSIPPI, OHIO, SOUTH CAROLINA, UTAH, WASHINGTON, WISCONSIN:

Approved Clinical Trials: Molina covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A Life-Threatening Disease or Condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify for coverage, an enrolled Member must be eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition, be accepted into an Approved Clinical Trial (as defined below) and have received Prior Authorization or approval from Molina. An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

1. The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, or a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or
2. The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. If a Member qualifies, Molina cannot deny their participation in an approved clinical trial. Molina cannot deny, limit, or place conditions on its coverage of Member's routine patient costs associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial.

The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that drug or the medication is typically provided free of charge to Members in the clinical trial.

Molina does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include: The investigational item, device or service itself, items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and any service inconsistent with the established standard of care for the patient's diagnosis.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. For Covered Services related to an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will pay the Cost Sharing they would pay if the services were not related to a clinical trial. Members should contact Member Services for further information.

IDAHO:

Approved Clinical Trials: Molina covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A Life-Threatening Disease or Condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify for coverage, an enrolled Member must be eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition, be accepted into an Approved Clinical Trial (as defined below) and have received Prior Authorization or approval from Molina. An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

1. The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, or a qualified non-governmental

- research entity identified in the guidelines issued by the National Institutes of Health for center support grants or
2. The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
 3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. If a Member qualifies, Molina cannot deny their participation in an approved clinical trial. Molina cannot deny, limit, or place conditions on its coverage of Member's routine patient costs associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial. The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that drug or the medication is typically provided free of charge to Members in the clinical trial.

Molina does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include: The investigational item, device or service itself, items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and any service inconsistent with the established standard of care for the patient's diagnosis.

For Covered Services related to an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will pay the Cost Sharing they would pay if the services were not related to a clinical trial. Members should contact Molina Customer Support for further information.

ILLINOIS:

Approved Clinical Trials: Molina covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A Life-Threatening Disease or Condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify for coverage, an enrolled Member must be diagnosed with cancer or other life-threatening disease or condition, be accepted into an Approved

Clinical Trial (as defined below) and have received Prior Authorization or approval from Molina. An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

- The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, or a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or
- The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. If a Member qualifies, Molina cannot deny their participation in an approved clinical trial. Molina cannot deny, limit, or place conditions on its coverage of Member's routine patient costs associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial. The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that drug or the medication is typically provided free of charge to Members in the clinical trial.

Molina does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include: The investigational item, device, or service itself, items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and any service inconsistent with the established standard of care for the patient's diagnosis.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. For Covered Services related to an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will pay the Cost

Sharing they would pay if the services were not related to a clinical trial. Members should contact Customer Support for further information.

KENTUCKY:

Approved Clinical Trials: Passport covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A Life-Threatening Disease or Condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify for coverage, an enrolled Member must be diagnosed with cancer or other life-threatening disease or condition, be accepted into an Approved Clinical Trial (as defined below) and have received Prior Authorization or approval from Passport. An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

1. The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, the U.S. Food and Drug Administration, or a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or
2. The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

Specifically, the clinical trial must do one of the following: (1) test how to administer a health care service, item, or drug for the treatment of cancer; (2) test responses to a health care service, item, or drug for the treatment of cancer; (3) compare the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer; or (4) study new uses of health care services, items, or drugs for the treatment of cancer.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. If a Member qualifies, Passport cannot deny their participation in an approved clinical trial. Passport cannot deny, limit, or place conditions on its coverage of Member's routine patient costs

associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial. The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that drug or the medication is typically provided free of charge to Members in the clinical trial. Passport does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act or Kentucky law, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include: The investigational item, device or service itself, items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and any service inconsistent with the established standard of care for the patient's diagnosis.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. For Covered Services related to an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will pay the Cost Sharing they would pay if the services were not related to a clinical trial. Members should contact Customer Support for further information.

NEW MEXICO:

Approved Clinical Trials: Molina only covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A life-threatening disease or condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify to participate in an approved clinical trial, an enrolled Member must be diagnosed with cancer or other life-threatening disease or condition and be accepted into an Approved Clinical Trial (as defined below). An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

- The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, or a qualified non-governmental research entity

identified in the guidelines issued by the National Institutes of Health for center support grants, or

- The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

If a Member qualifies, Molina cannot deny their participation in an approved clinical trial. Molina cannot deny, limit, or place conditions on its coverage of Member's routine patient costs associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial. The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that specific drug. Molina does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include:

- The investigational item, drug, device or service itself,
- Items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and
- Any service inconsistent with the established standard of care for the patient's diagnosis.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. For routine Covered Services while in an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will pay the Cost Sharing they would pay if the services were not performed during a clinical trial. Members should contact Member Services for further information.

TEXAS:

Approved Clinical Trials: Molina covers routine patient care costs for qualifying Members participating in approved clinical trials for cancer and/or another life-threatening disease or condition. A Life-Threatening Disease or Condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted. Members will never be enrolled in a clinical trial without their consent.

To qualify for coverage, an enrolled Member must be eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition, be accepted into an Approved Clinical Trial (as defined below) and have received Prior

Authorization or approval from Molina. An approved clinical trial means a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and:

- The study is approved or funded by one or more of the following: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, the U.S. Department of Defense, the U.S. Department of Veterans Affairs, or the U.S. Department of Energy, or a qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants or
- The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
- The study is conducted and approved by an institutional review board of an institution in this state that has an agreement with the Office for Human Research Protections of the United States Department of Health and Human Services, or
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. If a Member qualifies, Molina cannot deny their participation in an approved clinical trial. Molina cannot deny, limit, or place conditions on its coverage of Member's routine patient costs associated with their participation in an approved clinical trial for which they qualify. Members will not be denied or excluded from any Covered Services under this Agreement based on their health condition or participation in a clinical trial. The cost of medications used in the direct clinical management of the Member will be covered unless the approved clinical trial is for the investigation of that drug or the medication is typically provided free of charge to Members in the clinical trial. Molina does not have an obligation to cover certain items and services that are not routine patient costs, as determined by the Affordable Care Act, even when the Member incurs these costs while in an approved clinical trial. Costs excluded from coverage under this Plan include: The investigational item, device or service itself, items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, and any service inconsistent with the established standard of care for the patient's diagnosis. All approvals and Prior Authorization requirements that apply to routine care for Members not in an approved clinical trial also apply to routine care for Members in approved clinical trials. For Covered Services related to an approved clinical trial, Cost Sharing will apply the same as if the service were not specifically related to an approved clinical trial. Members will

pay the Cost Sharing they would pay if the services were not related to a clinical trial. Members should contact Customer Support for further information.

D. NOT COVERED

Refer to the member’s Evidence of Coverage (EOC) and Schedule of Benefits (SOB) to determine coverage eligibility.

EXPERIMENTAL OR INVESTIGATIONAL SERVICES

CALIFORNIA, FLORIDA, ILLINOIS, KENTUCKY, MICHIGAN, MISSISSIPPI, NEW MEXICO, OHIO, SOUTH CAROLINA, TEXAS, UTAH, WISCONSIN:

Molina and Passport do not cover Experimental or Investigational services; however, this exclusion does not apply to Services covered under Approved Clinical Trials

IDAHO, WASHINGTON:

Experimental or Investigational Services: Any medical service including procedures, medications, facilities, and devices that Molina has determined have not been demonstrated as safe or effective compared with conventional medical services. In determining whether services are Experimental or Investigational, Molina will consider whether the services are in general use in the medical community in the State of Idaho, whether the services are under continued scientific testing and research, whether the services show a demonstrable benefit for a particular illness or disease, and whether they are proven to be safe and efficacious.

This exclusion does not apply to any of the following:

- Services covered under “Approved Clinical Trials” in the Covered Services section of this Agreement.

Please refer to the “External Review or Appeal” section for information about Independent Medical Review related to denied requests for Experimental or Investigational services.

E. DEFINITIONS

[See Glossary](#)

F. POLICY HISTORY/REVISION INFORMATION

| Date | Action/Description |
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|----------------------------|---|--|------------|---------------------|
| | 4/15/2021 | <ul style="list-style-type: none"> Added KY 2022 Drafted Language | | |
| | 5/14/2021 | <ul style="list-style-type: none"> Added IL 2022 EOC Language | | |
| | 6/28/2021 | <ul style="list-style-type: none"> Added ID 2022 EOC Language | | |
| | | <ul style="list-style-type: none"> | | |
| Procedure Codes | None | | | |
| Prior Authorization | <p>For the MHI PA Matrix, if a code is NOT listed, it could EITHER be:</p> <ol style="list-style-type: none"> Covered and No PA Required Not Covered <p>You cannot use the MHI PA Matrix to make coverage determinations.</p> <p>PA Lookup Tool</p> | | | |
| Approval | Departments | Product | CIM | Clinical Management |
| | Date (Initial) | 12/22/2020 | 12/18/2020 | 3/16/2021 |
| | Revised (for 1/1/2022) | 10/21/2021 | | 10/21/2021 |