POLICY AND PROCEDURE MANUAL

Policy Title: Experimental and Investigational Procedures	**Policy Number: I.16**
Primary Department: Medical Management **Affiliated Department(s): N/A**	**NCQA Standard: N/A** **URAC Standard: N/A**
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Applicable Lines of Business: ☐MeridianCare ☒MeridianHealth ☐MeridianComplete ☒MeridianChoice	
Applicable States: ☐All ☒MI ☒IL ☐OH ☐_____ ☐_____	
Applicable Programs: ☒All ☐Other _____	
Policy is to be published: Internally Only ☐ Internally & Externally ☒	

Definitions:

Experimental and investigational	A procedure, device or pharmaceutical agent that is still undergoing pre-clinical or clinical evaluation, and/or has not yet received regulatory approval**.** It is the use of a service, procedure or supply that is not recognized by the Plan as standard medical care for the condition, disease, illness or injury being treated. A service, procedure or supply includes but is not limited to the diagnostic service, treatment, facility, equipment, drug or device. When basic safety and efficacy have been demonstrated by the experimental scientific process, the investigational phase begins.
Reliable Evidence	Published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, treatment or procedure.
Promising	Preliminary scientific data supports reasonable likelihood of success of the treatment for the diagnosis.
Clinical Trial and Trial Phases	A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called clinical study. Each phase is a part of the clinical research process that answers specific questions about whether treatments that are being studied work and are safe. Phase I trials test the best way to give a new treatment (e.g. oral or IV), side effects and the best dose. Phase II trials test whether a new treatment has an effect on the disease. Phase III trials compare the results of people taking a new treatment with the results of people taking the standard treatment. Phase IV trials are done using thousands of people after a treatment has been approved and marketed, to check for side effects that were not seen in the phase III trial.
Clinical Trials for Investigational	(*from the Food & Drug Administration*) *Phase I*— Testing concerned primarily with the safety of the drug and normally done on a small number (20-100) of healthy volunteers. The goal during this phase is to determine the drug's most frequent and serious adverse effects and how the drug is metabolized

New Drugs	and excreted. *Phase II*— This phase of drug testing involves a few hundred patients and is designed to show whether the drug is effective in treating the disease or condition for which it is intended. Most Phase II studies are randomized controlled trials in which the participants taking the drug are compared to similar participants receiving a different treatment, placebo or different drug. Safety and short-term adverse effects are studied. . *Phase III*— The population size is expanded to several hundred to several thousand to clarify the drug's benefit-risk relationship and discover side effects and adverse reactions. These three phases are necessary for FDA marketing approval of a new drug. Post marketing surveillance (*Phase IV*) is done to detect adverse reactions that might not have been detected in earlier trials.

Policy:
Meridian will not provide coverage for experimental/investigational services, procedures or supplies and will not reimburse for any services, procedures, drugs or supplies associated with those experimental, investigational, cosmetic, or not medically necessary services. Experimental/Investigational services do not meet the criteria for medically necessary services because these services are not standard medical practice (See Medical Necessity Policy).

Procedure:
Criteria for Coverage:
Services, procedures, devices, supplies, and/or treatments are considered experimental/ investigational by MHP if any one of the following criteria is met:

1. The requested drug or device has not been granted approval by the Food and Drug Administration (FDA) to be lawfully marketed in the United States.
2. The requested drug or device or medical supply has not received unrestricted market approval from the Food and Drug Administration (FDA) or other relevant governmental oversight body for use in treating the specific medical condition in question. MHP does not consider an interim approval by the FDA as an acceptable substitute for final unrestricted market approval.
3. The drug, device, treatment or procedure is provided pursuant to oversight by an institutional review board or other body that approves or reviews research concerning safety, toxicity or efficacy.
4. Patient informed consent documents describe the drug, device, treatment or procedure as experimental or investigational or otherwise under evaluation for safety, toxicity or efficacy.
5. There is inadequate or inconclusive evidence in peer-reviewed medical/scientific literature supporting the therapeutic efficacy and/or safety of the service, medication, procedure or device (Adequate evidence is defined as **at least two** documents of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member.) SEE APPENDIX.
6. There is inadequate or inconclusive evidence in peer-reviewed medical/scientific literature showing that the requested service, medication, procedure or device offers at least equivalent clinical efficacy/outcomes to established therapeutic alternatives. (Adequate evidence is defined as **at least two** documents of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member.) SEE APPENDIX.
7. **Reliable Evidence** shows that the drug, device, treatment or procedure is the subject of on-going Phase I or Phase II clinical trials; is the research, experimental, study or investigational arm of on-going Phase III clinical trials; or is otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.
8. **Reliable Evidence** shows that the prevailing opinion among experts regarding the drug, device, treatment or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis.

Experimental Drugs/Off Label Use of Drugs:
All of the following criteria must be met for approval of the use of drugs **outside of** FDA approved indications:

1. The drug is **approved** by the Federal Food and Drug Administration for at least one indication.
2. The drug is prescribed by physician licensed practitioner for the treatment of either of the following:
    a. **A life-threatening condition** provided that the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the MHP's formulary procedures

b. **A chronic and seriously debilitating condition** provided that the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the MHP's formulary procedures

3. The drug has been recognized for the treatment of the condition for which it is prescribed by **all** of the following:
    a. The American Medical Association Drug Evaluations.
    b. The American Hospital Formulary Service for Drug Information
    c. The United States Pharmacopoeia Dispensing Information
    d. DrugDex
    e. Clinical Pharmacology
    f. The requested medication is considered the Standard of Care as evidenced by accepted Clinical Practice Guidelines developed by the appropriate medical specialty and supported by at least two peer-reviewed journal articles that are: randomized, prospective, double-blinded, against placebo and/or alternative standard therapy
4. Current clinical documents must be submitted. When medical records are requested, letters of support and or explanation are often useful but are not sufficient documentation unless all specific information is needed to make a medical necessity determination is included. Required medical information will include:
    a. Current chart notes documenting the member's condition
    b. Chart notes documenting the member's past medical history
    c. Documentation of compliance with scheduled office visits and medical care
    d. Lab and or test results as required to support need for medication.
    e. Documentation that all medications FDA Approved for the indication have been adequately tried and failed, or are contraindicated
5. A Clean Drug Screening is obtained from the member.
6. Member would not be authorized if there are any known contraindications to the medication. Experimental or off label drugs would not be approved if the member does not meet these criteria. Initial approval is for one month. Criteria for continuation of therapy requires evidence of compliance with therapy and that the criteria outlined above continue to be fulfilled. Criteria for discontinuation of therapy requires documentation that the member is non-compliant with medical or pharmacologic therapy or that there is no improvement in the clinical condition after the initiation of the drug therapy.

Line of Business Applicability:
This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual plans.

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html), or the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx). If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), or the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx) the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

State specific special instructions:

None: ☐

MI:

IL: Medicaid : Routine care for phases 3 & 4 of cancer trials will be covered so long as there is a signed attestation from the hospital stating that the member is not eligible for reimbursement from any other source.

OH:

Individual Plans:

- We cover routine patient costs in connection with certain approved clinical trials as provided in the Certificate of Coverage.
- We will conduct an individual case review to determine if investigational care will be covered

References:

1. Michigan Department of Human Services Medicaid Provider Manual. General Information for Providers. Section 8.3. Revised: October 1, 2017
2. Illinois Department of Health and Family Services. Practioners Handbook for Practitioners Rendering Medical Services, Chapter A-200 Policy & Procedures for Medical Services (Issue Date: October, 2016).
3. Department of Health and Human Services. Medicare Learning Network: Items and Services that are Not Covered Under the Medicare Program. Revised: January, 2015.Medicare Benefit Policy Manual. Chapter 16 – General Exclusions from Coverage. Revised: Novembet 6, 2014.
4. National Cancer Institute. NCI Dictionary of Cancer Terms.

State Letters/Bulletins					
CMS National/Local Coverage Determination (NCD/LCD)					
Medicare Managed Care Manual:					
Medicaid CFR:					
State Administrative Codes:					
Contract Requirements:					
Related Policies:					

Appendix

Medical and Scientific Evidence is defined by MHP as one of the following:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
2. Peer-reviewed literature or biomedical compendia from such sources as the National Institute of Health's National Library of Medicine or The Cochrane Library.
3. An accepted indication for treatment in one of the following standard reference compendia:
   - The American Hospital Formulary Service-Drug Information,
   - The American Medical Association Drug Evaluations,
   - The American Dental Association Accepted Dental Therapeutics, and
   - The United States Pharmacopoeia Drug Information.
4. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
   - U.S. Department of Health and Human Services,
   - Federal Agency for Healthcare Research and Quality,
   - National Institutes of Health,
   - National Cancer Institute,
   - National Academy of Sciences,
   - Center for Medicare and Medicaid Services, and
   - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.