DOCUMENT REVISION HISTORY LOG

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MEMORIAL HERMANN HEALTH PLAN HOLDINGS, LLC
POLICY

POLICY TITLE: MHHP MEDM-MA ONC-009 Preferred Oncology Drugs

PUBLICATION DATE: 05/26/2025
LAST REVIEW DATE: 05/26/2025
VERSION: 1

Version	*Change Summary*	*Revised By*
1	Legacy document; Approved by P&T Committee 3/19/25	S. Soman/ M. Gorek-Yaraghi

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POLICY PURPOSE:

The purpose of this policy is to define the clinical criteria for the coverage for oncology medications under medical (including, but not limited to chemotherapy, immunotherapy, targeted therapies, oral oncolytics, leucovorin, gonadotropin releasing hormonal analogs, bone modifying agents, somotostatin analogs, white blood cell growth factors, red blood growth factors, other supportive drugs). This coverage policy addresses medications used for the primary treatment of cancer. The use of oncology agents for non-oncology uses are addressed in separate coverage policies. The preferred oncology products listed should be used unless there is a specific medical reason contraindicating their use. Coverage determination may also be directed by the Centers of
Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD) or Local Coverage Determinations (LCD), and/or health plan specific drug coverage policies where applicable. For off- label indications, refer to the off-label and NCCN policies for coverage review. This policy
supplements Medicare NCDs, LCDs, and manuals for the purpose of determining coverage under Medicare Part B benefits. A member cannot be required under this policy to change a current
drug/product. For the purposes of this policy, a current drug/product means the member has a paid claim for the drug/product within the past 365 days. If a provider administers a non-preferred
drug/product without obtaining prior authorization, Memorial Hermann Health Plan may deny claims for the non-preferred drug/product. The criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD).

DEFINITIONS:

Brand Name Drug: The first version of a particular medication to be developed or a medication that is sold under a pharmaceutical manufacturer's own registered trade name or trademark. The original manufacturer is granted a patent, which allows it to be the only company to make and sell the new drug for a certain number of years.

Centers for Medicare & Medicaid Services (CMS): MS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS

works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.

CMS Recognized Compendia: The Centers for Medicare and Medicaid Services (CMS) recognizes several compendia for determining if a drug or biological is medically accepted for off-label use. The CMS uses these compendia to determine if a drug or biological is medically accepted for off-label use in anti-cancer chemotherapeutic regimens.

Food and Drug Administration (**FDA):** An agency of the United States federal government responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products. The FDA's main goal is to ensure that these products are safe and effective for their intended use, and that their labeling and marketing are truthful and not misleading.

Generic Drugs: Prescription Drugs that have been determined by the Food and Drug Administration (FDA) to be equivalent to Brand Name Drugs but are not made or sold under a registered trade name or trademark. Generic Drugs have the same active ingredients, meet the same FDA requirements for safety, purity, and potency and must be dispensed in the same dosage form (e.g., tablet, capsule, cream) as the Brand Name Drug.

Off Label Drug: The prescription and administration of a medication for a purpose, dosage, or patient population that is not approved by the regulatory agency Food and Drug Administration (FDA).

SCOPE:

This policy applies to Memorial Hermann Medicare plans.

POLICY STATEMENT

The Policy for Preferred Oncology Drug Utilization Standards provides parameters for coverage of injectable oncology medications covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, panel review and
levels of evidence. This policy does not supersede policies issued to specific cases such as off- label usage policies or biosimilar usage policies. Drugs/products must satisfy the criteria in this policy for preferred oncology drugs/products and, if approved,

authorization will be provided for up to 12 months if supported by treatment guidelines or FDA labeling.

Applicability:
The drug list below is not all inclusive, any drugs that have an oncology indication may fall under this criteria. These drugs have UM requirements for Prior Authorization (PA). Quantity Limits may apply.

HCPCS	Generic Name	Brand Name
J9000	Doxorubicin Hydrochloride	Adriamycin
J9015	Aldesleukin	Proleukin
J9017	Arsenic Trioxide	Trisenox
J9019	Asparaginase (Erwinaze)	Erwinase
J9020	Asparaginase, Not Otherwise Specified	Elspar, Kidrolase
J9021	Asparaginase Erwinia Chrysanthemi (Recombinant)-Rywn	Rylaze
J9022	Atezolizumab	Tecentriq
J9023	Avelumab	Bavencio
J9025	Azacitidine	Vidaza
J9027	Clofarabine	Clolar
J9029	Instill Adstiladrin, Tx Dose	Adstiladrin
J9030	Bcg Live Intravesical Instillation	Tice Bcg
J9032	Belinostat	Beleodaq
J9033	Bendamustine Hcl (Treanda)	Treanda
J9034	Bendamustine Hcl (Bendeka)	Bendeka

J9035	Bevacizumab	Avastin
J9036	Bendamustine Hydrochloride, (Belrapzo)	Belrapzo
J9037	Belantamab Mafodotin- Blmf	Blenrep
J9039	Blinatumomab	Blincyto
J9040	Bleomycin Sulfate	Blenoxane; Bleo 15k
J9041	Bortezomib (Velcade)	Velcade
J9042	Brentuximab Vedotin	Adcetris
J9043	Cabazitaxel	Jevtana
J9044	Bortezomib, Not Otherwise Specified	Bortezomib
J9045	Carboplatin	Paraplatin
J9047	Carfilzomib	Kyprolis
J9046	Inj. Bortezomib, Dr. Reddy's	Bortezomib
J9048	Inj. Bortezomib Freseniuskab	Bortezomib
J9049	Inj. Bortezomib, Hospira	Bortezomib
J9050	Carmustine	Bicnu
J9052	Inj. Carmustine (Accord)	Carmustine
J9055	Cetuximab	Erbitux
J9056	Inj Bendamustine, 1 Mg	Vivimusta
J9057	Copanlisib	Aliqopa
J9058	Inj Apotex/Bendamustine 1 Mg	Bendamustine (Apotex)

J9059	Inj Bendamustine, Baxter 1mg	Bendamustine Hydrochloride
J9060	Cisplatin, Powder Or Solution	Platinol
J9061	Amivantamab	Rybrevant
J9063	Inj Elahere, 1 Mg	Elahere
J9065	Cladribine	Leustatin
J9070	Cyclophosphamide	Cytoxan
J9071	Cyclophosphamide (Auromedics)	Cytoxan
J9072	Inj Cyclophos (Dr.Reddy's) 5mg	Cyclophosphamide (Dr. Reddy's)
J9100	Cytarabine	Cytostar; Tarabine Pfs
J9118	Calaspargase Pegol-Mknl	Asparlas
J9119	Cemiplimab-Rwlc	Libtayo
J9120	Dactinomycin	Cosmegen
J9130	Dacarbazine	Dacarbazine
J9144	Daratumumab And Hyaluronidase-Fihj	Darzalex Fastpro
J9145	Daratumumab	Darzalex
J9150	Daunorubicin	Cerubidine
J9151	Daunorubicin Citrate, Liposomal Formulation	Daunoxome
J9153	Daunorubicin (1 Mg) And Cytarabine (2.27 Mg), Liposomal	Vyxeos
J9155	Degarelix	Firmagon

J9160	Denileukin Diftitox	Ontak
J9171	Docetaxel	Taxotere
J9173	Durvalumab	Imfinzi
J9175	Elliotts' B Solution	Elliotts' B Solution
J9176	Elotuzumab	Empliciti
J9177	Enfortumab Vedotin-Ejfv	Padcev
J9178	Epirubicin Hcl	Ellence
J9179	Eribulin Mesylate	Halaven
J9181	Etoposide	Etopophos
J9185	Fludarabine Phosphate	Fludara
J9190	Fluorouracil	Adrucil
J9196	Inj Gemcitabine Hcl (Accord)	Gemcitabine
J9198	Gemcitabine Hydrochloride (Infugem)	Infugem
J9200	Floxuridine	Fudr
J9201	Gemcitabine Hydrochloride	Gemcitabine
J9202	Goserelin Acetate Implant	Zoladex
J9203	Gemtuzumab Ozogamicin	Mylotarg
J9204	Mogamulizumab-Kpkc	Poteligeo
J9205	Irinotecan Liposome	Onivyde
J9206	Irinotecan	Camptosar
J9207	Ixabepilone	Ixempra
J9208	Ifosfamide	Ifex

J9209	Mesna	Mesnex
J9210	Emapalumab-Lzsg	Gamifant
J9211	Idarubicin Hydrochloride	Idamycin Pfs
J9212	Interferon Alfacon-1, Recombinant	Infergen
J9213	Interferon, Alfa-2a, Recombinant	Roferon-A
J9214	Interferon, Alfa-2b, Recombinant	Intron A
J9215	Interferon, Alfa-N3, (Human Leukocyte Derived)	Alferon N
J9216	Interferon, Gamma 1-B, 3 Million Units	Actimmune
J9217	Leuprolide Acetate (For Depot Suspension)	Eligard; Lupron Depot
J9223	Lurbinectedin	Zepzelca
J9225	Histrelin Implant (Vantas)	Vantas
J9228	Ipilimumab	Yervoy
J9229	Inotuzumab Ozogamicin	Besponsa
J9230	Mechlorethamine Hydrochloride, (Nitrogen Mustard)	Mustargen
J9245	Melphalan Hydrochloride, Not Otherwise Specified	Melphalan Hydrochloride, Nos
J9246	Melphalan Hydrochloride	Evomela
J9247	Melphalan Flufenamide	Pepaxto
J9250	Methotrexate Sodium	Methotrexate

J9259	Paclitaxel (American Regent)	Paclitaxel Protein-Bound (American Regent)
J9260	Methotrexate Sodium	Methotrexate
J9261	Nelarabine	Arranon
J9262	Omacetaxine Mepesuccinate	Synribo
J9263	Oxaliplatin	Eloxatin
J9264	Paclitaxel Protein-Bound Particles	Abraxane
J9266	Pegaspargase	Oncaspar
J9267	Paclitaxel	Taxol
J9268	Pentostatin	Nipent
J9269	Tagraxofusp-Erzs	Elzonris
J9270	Plicamycin	Mithracin
J9271	Pembrolizumab	Keytruda
J9272	Dostarlimab-Gxly	Jemperli
J9273	Tisotumab Vedotin-Tftv	Tivdak
J9274	Inj. Tebentafusp-Tebn, 1 Mcg	Kimmtrak
J9280	Mitomycin	Mutamycin
J9281	Mitomycin Pyelocalceal Solution	Jelmyto
J9285	Olaratumab	Lartruvo
J9286	Inj Glofitamab Gxbm, 2.5 Mg	Columvi
J9293	Mitoxantrone Hydrochloride	Novantrone

J9294	Inj Pemetrexed, Hospira	Pemetrexed
J9295	Necitumumab	Portrazza
J9296	Inj Pemetrexed	Pemetrexed
J9297	Inj Pemetrexed (Sandoz)	Pemetrexed
J9298	Inj Nivol Relatlimab 3mg/1mg	Opdualag
J9299	Nivolumab	Opdivo
J9301	Obinutuzumab	Gazyva
J9302	Ofatumumab	Arzerra
J9303	Panitumumab	Vectibix
J9304	Pemetrexed	Pemfexy
J9305	Pemetrexed, Nos	Alimta
J9306	Pertuzumab	Perjeta
J9307	Pralatrexate	Folotyn
J9308	Ramucirumab	Cyramza
J9309	Polatuzumab Vedotin-Piiq	Polivy
J9311	Rituximab And Hyaluronidase	Rituxan Hycela
J9312	Rituximab	Rituxan
J9313	Moxetumomab Pasudotox-Tdfk	Lumoxiti
J9314	Inj Pemetrexed (Teva) 10mg	Pemetrexed
J9316	Pertuzumab And Trastuzumab Hyaluronidase	Phesgo
J9317	Sacituzumab govitecan-hziy	Trodelvy

J9318	Romidepsin, Non-Lypohilized (E.G. Liquid)	Istodax
J9319	Romidepsin, Lymphilized	Istodax
J9320	Streptozocin	Zanosar
J9321	Inj Epcoritamab-Bysp 0.16 Mg	Epkinly
J9323	Inj Pemetrexed (Hospira) 10	Pemetrexed (Hospira)
J9325	Talimogene Laherparepve	Imlygic
J9328	Temozolomide	Temodar
J9330	Temsirolimus	Torisel
J9331	Inj. Sirolimus Prot Part 1 Mg	Fyarro
J9340	Thiotepa	Tepadina
J9345	Inj.. Retifanlimab-Dlwr, 1 Mg	Zynyz
J9348	Naxitamab-Gqgk	Danyleza
J9349	Tafasitamab-Cxix	Monjuvi
J9350	Inj.. Mosunetuzumab-Axgb, 1 Mg	Lunsumio
J9351	Topotecan	Hycamtin
J9352	Trabectedin	Yondelis
J9353	Margetuximab-Cmkb	Margenza
J9354	Ado-Trastuzumab Emtansine	Kadcyla
J9355	Trastuzumab	Herceptin
J9356	Trastuzumab And Hyaluronidase-Oysk	Herceptin Hylecta

J9357	Valrubicin, Intravesical	Valstar
J9358	Fam-Trastuzumab Deruxtecan-Nxki	Enhertu
J9359	Loncastuximab Tesirine-Lpyl	Zynlonta
J9360	Vinblastine Sulfate	Vinblastine
J9370	Vincristine Sulfate	Vincasar
J9371	Vincristine Sulfate Liposome	Marqibo
J9380	Inj. Teclistamab Cqyv 0.5 Mg	Tecvayli
J9390	Vinorelbine Tartrate	Navelbine
J9393	Inj. Fulvestrant (Teva)	Fulvestrant
J9394	Inj. Fulvestrant (Fresenius)	Fulvestrant
J9395	Fulvestrant	Faslodex
J9400	Ziv-Aflibercept	Zaltrap
J9600	Porfimer Sodium	Photofrin
Q2017	Doxil	Teniposide
Q2043		Sipuleucel-T Autologous Cd54+ Cells
Q2049	Mvasi	Doxorubicin Hydrochloride, Liposomal, Imported Lipodox
Q2050	Ontruzant	Liposomal Doxorubicin
Q2056	Herzuma	Carvykti
Q5107	Ogivri	Bevacizumab-Awwb,Biosimilar (Mvasi)
Q5112	Truxima	Trastuzumab-Dttb, Biosimilar, (Ontruzant)

Q5113	Trazimera	Trastuzumab-Pkrb, Biosimilar, (Herzuma)
Q5114	Kanjinti	Trastuzumab-Dkst, Biosimilar, (Ogivri)
Q5115	Zirabev	Rituximab-Abbs, Biosimilar (Truxima)
Q5116	Ruxience	Trastuzumab-Qyyp, Biosimilar (Trazimera)
Q5117	Riabni	Trastuzumab-Anns, Biosimilar, (Kanjinti)
Q5118	Inj. Releuko 1 Mcg	Bevacizumab-Bvzr, Biosimilar, (Zirabev)
Q5119	Inj. ALYMSYS, 10 MG	Rituximab-Pvvr
Q5123	Inj. Stimufend, 0.5 Mg	Rituximab-Arrx
Q5125	Inj. Vegzelma, 10 Mg	Releuko
Q5126	Inj. bevacizumab-maly	Alymsys
Q5127	Inj. pegfilgrastim-fpg	Stimufend
Q5129	Inj. bevacizumab-adcd	Vegzelma
J9999	Not Otherwise Classified, Antineoplastic Drugs	Injectable Chemotherapy Drugs That Have Not Yet Received An Assigned Code And Billed Under A Miscellaneous Hcpcs Code.
J3590	Unclassifed Biologics	Injectable Chemotherapy Drugs That Have Not Yet Received An Assigned Code And Billed Under A Miscellaneous Hcpcs Code.
J3490	Unclassifed Drug	Injectable Chemotherapy Drugs That Have Not Yet Received An Assigned Code And Billed Under A Miscellaneous Hcpcs Code.

Non Preferred Product Criteria

Initial Authorization Criteria
Product: Non-Preferred Oncology Products
Approval Length: 12 Month(s)
Guideline Type: Prior Authorization
Approval Criteria

1. Requested reference drug has been approved as safe and effective by the U.S. Food and Drug Administration (FDA) for at least ONE indication in the United States.

AND

2. The requested product or drug is for an oncology indication approved by the FDA

AND

3. The provider must submit medical records documenting the following for the reference product:
    a. Documentation member has tried and failed or has a contraindication to a preferred oncology product for the member's diagnosis.

    OR

    b. Documentation member has tried and failed, or has a contraindication to, all the preferred oncology drugs or products on the preferred listed products/drugs list for the same requested indication or products/drugs which are considered to be standard of care, and which are of equal or greater efficacy compared to the requested agent for the member's diagnosis.

AND

4. The reference product requested is not being requested for off-label use.
    a. A drug is considered off-label if the diagnosis requested is not listed in the package insert of the drug or in the FDA-approved indications list in a CMS recognized compendia.

    Note: If requested for off-label, it must be reviewed with off-label policy in addition to this non-preferred oncology product.

AND

5. Prescriber attests to (or the clinical reviewer has found that) the member not

having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review AND the requested drug is not contraindicated by the FDA for the requested indication.

AND

6. Prescriber attests to baseline and regular ongoing safety monitoring per FDA label for the requested drug.

AND

7. This is being Prescribed by an appropriate specialist for the indication requested.

AND

8. The requested dosage does not exceed age-appropriate quantity limits or other safety limits

Additional Notes:
Initial authorization: up to 12 months; duration of therapy needs to be supported by the manufacturer's prescribing information or compendia.
Age Restrictions: Not to exceed limits in compendia or articles provided

Site of Care: Infusions must occur in an outpatient infusion center unless medically necessary
(e.g., high risk of infusion reactions requiring inpatient monitoring). Please refer to this policy for additional information.

Non-Preferred Product Reauthorization Criteria

Reauthorization Criteria
Product: Non-Preferred Oncology Products
Approval Length: 12 Month(s)
Guideline Type: Prior Authorization
Approval Criteria

1. The request is not for continuation of therapy of medications for a non-preferred oncology product for new Memorial Hermann Health Plan members: Initial criteria must be met.

AND

2. One of the following for the non-preferred oncology product:
   a. Adherence to therapy at least 75% of the time as verified by the prescriber or member medication fill (or claim) history. **OR**

   b. Adherence less than 75% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation.

AND

3. Prescriber attests to or the clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity.

AND

4. Documentation of a positive clinical response to therapy (e.g., improvement in laboratory parameters or disease state response or other clinical evidence of positive benefit) with submitted medical records (such as office chart notes, lab results or other clinical information).

AND

5. Prescriber attests to ongoing safety monitoring per FDA label for the requested drug.

AND

6. The requested dose does not exceed quantity limits or other safety limits.

Additional Notes:
Reauthorization: Up to 12 months maximum. Duration of therapy needs to be supported by the manufacturer's prescribing information or compendia or treatment regimen.
Age Restrictions: Not to exceed limits in compendia or articles provided

Site of Care: Infusions must occur in an outpatient infusion center unless medically necessary (e.g., high risk of infusion reactions requiring inpatient monitoring). Please refer to this policy for additional information.

Non-Preferred Product Quantity Limit Criteria

Quantity Limit Criteria
Product: Non-Preferred Oncology Products
Approval Length: Through the end of Plan Year
Guideline Type: Quantity Limit
Approval Criteria

1. One of the following:
   a. Quantity limit override requests must involve an FDA-approved indication

   OR

   b. Quantity limit override requests involving off-label indications must meet off-label guideline requirements (initial criteria for new starts or reauthorization criteria for continuation of therapy)

AND

2. One of the following:
   a. The higher dose or quantity is supported in the drug labeling (dosage and administration section of the manufacturer's prescribing information);

OR

b. The higher dose or quantity is supported by one of the Medicare approved compendia: i. The American Hospital Formulary Service Drug Information (AHFS-DI), ii. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium iii. DRUGDEX System by Micromedex, iv. National Comprehensive Cancer Network (NCCN) Compendium v. Elsevier Gold Standard's Clinical Pharmacology
Additional Notes: Higher dosing may be accepted if the provider supplies medical references or literature that is peer-reviewed showing support for the safety and efficacy of the drug at the dose requested. Can approve until treatment duration if provided by provider in the submitted medical records for shorter duration approvals. **Site of Care:** Infusions must occur in an outpatient infusion center unless it is medically necessary to administer in other places of service (e.g., high risk of infusion reactions requiring inpatient monitoring).

Medicare Part B vs Part D

Medications covered under Medicare can be classified into two broad coverage categories: those covered under the outpatient pharmacy benefit (aka Part D- Medicare) (a written prescription is processed and dispensed at a local or mail order pharmacy for the patient to self-administer at home) and those covered under the medical benefit (aka Part B – Medicare) (usually administered by a healthcare professional during a physician office or clinic visit or as part of an outpatient procedure). Drugs covered under a medical benefit are usually limited to drugs or biologicals administered by infusion or injection. However, if a drug is self-administered by injection (e.g. insulin) they are not covered as medical (Part B) benefits. The place where the drug is administered also dictates how the medication is covered (i.e. inpatient stay vs skilled-nursing facility vs patient's home). Please refer individual CMS LCD/LCA Self-Administered Determination Guideline Articles for further details: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52571&ver=126

Categories of Evidence

Memorial Hermann Health Plan accepts the following levels of evidence from compendia:

1. Elsevier Gold Standard's Clinical Pharmacology: The narrative text is supportive of the requested off-label use and noted as a 'Strong Recommendation.'

Recommendations noted as ‘Equivocal/Weak’ are not considered supportive of an off-label indication.

2. American Hospital Formulary Service-Drug Information (AHFS-DI): The narrative text in AHFS-DI is supportive of the requested off-label use.
   NOTE: The "dagger" symbol is used to indicate off-label drug use by the American Hospital Formulary Service Drug Information® (AHFS®, Bethesda, MD). If AHFS indicates an off-label use but qualifies that statement with "but additional study is needed" or "further study is needed to evaluate safety and efficacy", the qualifying language does not support an off-label indication as medically necessary.
3. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium: Recommendations noted as ‘Equivocal or Against Proposed off label use’ are not considered supportive of an off-label indication.
4. National Comprehensive Cancer Network Compendium (NCCN): MHI recognizes Category 1 and 2 A approvals. Category 2b may be reviewed on a case-by-case basis by the medical director for appropriate support.
5. Micromedex DrugDex: MHI recognizes Class I and IIa strength of recommendation. Class IIb may be reviewed on a case-by-case basis by the medical director for appropriate support.

NOTE: The complete absence of narrative text on a use or a requested indication is considered neither supportive nor non-supportive.

Journals Accepted for Reference

Off-label use of drugs or regimens may also be considered medically accepted if supported as safe and effective according to peer-reviewed articles eligible for coverage from one of the following journals:

- American Journal of Hematology
- Annals of Pharmacotherapy
- Blood (ASH Journal)
- Clinical Cancer Research (AACR Journal)
- Clinical Pharmacology & Therapeutics
- JAMA Oncology
- Journal of Clinical Oncology (JCO)
- Journal of Immunotherapy

- Journal of the American Medical Association (JAMA)
- Nature Reviews Drug Discovery
- New England Journal of Medicine (NEJM)
- The Lancet

The articles submitted should meet the following requirements to be accepted:

1. Journals should be published **within the last 5 years** to ensure up-to-date clinical validity. If there are no recent studies that exist within 5 years, systematic reviews older than 5 years may still be accepted if – they remain gold standard for a specific off-label use and/or they have been cited in recent guidelines or compendia (ex. NCCN, ASCO, ACR).

2. Phase III randomized, placebo-controlled studies with subject size sufficient to determine statistical validity [Published studies required] or an adequate number of well-designed studies with sufficient numbers of subjects in relation to the incidence or prevalence of the disease

   NOTE: *Peer-Review Medical Literature: Off-label uses that are supported by clinical research peer-reviewed medical literature that may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. Memorial Hermann Health Plan considers any drug being studied in a phase I or phase II clinical trial or use that is based solely on evidence from a phase I or phase II clinical trial, investigational. All submitted studies must be published Phase III randomized, placebo-controlled studies with subject size sufficient to determine statistical validity.

3. Published in the regular editions of the journals that publish original manuscripts only after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity, and reliability.

   NOTE: If ANY of the below are met, evidence is considered insufficient. Articles submitted must not be in the form of:

   - A special supplement or publication and not to include publications privately funded by parties (i.e., manufacturers of the product) with a vested interest in the recommendations and provides full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization

- In-house publications by pharmaceutical manufacturing companies or abstracts (including meeting abstracts) are not considered peer review medical literature
- Retrospective studies, opinion statements, case reports, letters to the editor, abstracts of a publication, reports of Phase I or Phase II trials are not sufficient.
  *In general, case reports are considered uncontrolled, are based on anecdotal information, and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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DrugDex® System (database online). Greenwood Village, CO: Thomson Micromedex. Available at: http://www.micromedexsolutions.com.

Facts and Comparisons® (database online). St. Louis, MO: Wolters Kluwer Health, Inc. Available at: http://www.factsandcomparisons.com.

National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (database online). Available at: http://www.nccn.org.

U.S. Food and Drug Administration (FDA). Off-label and investigational use of marketed drugs, biologics, and medical devices. Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm.