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 Policy Number: C16154-A

Standard Oncology Criteria

PRODUCTS AFFECTED

See dosage forms

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

N/A

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information,

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Drug and Biologic Coverage Criteria

DRUGDEX Information System, National Comprehensive Cancer Network (Categories 1 or 2A only), or pediatric consortium (e.g., Children's Oncology Group [COG], St. Jude Consortium, Dana-Farber Cancer Institute [DFCI]).

(NOTE: A category 2B therapy/regimen may be authorized on an exception basis with documented Molina Healthcare medical director or Molina Healthcare oncologist consultation)

AND

2. Documentation of dose and dates of all previous therapies and the resulting outcomes where applicable
AND
3. Documentation that the proper succession of the therapies has been considered OR have been tried and failed (i.e., serious side effects, contraindication, or progression)
(NOTE: The proper succession for this element can be found within compendia monographs, FDA label or NCCN guidelines; If compendia monographs, FDA label or NCCN guidelines have a formulary/preferred product at therapeutic parity with requested agent a formulary/preferred product should be used first where state regulations allow.)
AND
4. Documentation of related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment.
AND
5. Molina reviewer has verified if this product is included in the split fill program and has adjusted the day supply based on clinical appropriateness and authorization set up with the appropriate specialty pharmacy (Fill #1: one 14 or 15-day supply, Fill #2: one 14 or 15- day supply, fill #3: one 14 or 15-day supply, fill #4: one 14- or 15-day supply, Fill #5 one 14 or 15 day supply, Fill #6 one 14 or 15 day supply, Fill #7 28/30 day supply based on package size)
Molina reviewers and delegates will comply with all regulations and requirements applicable to the review of the request, providing exception to our standard criteria as may be required under state regulations and requirements.
AND
6. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
[DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]
OR
7. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
 - a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, or is contraindicated (i.e., an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient diary or medical charted notes)
[DOCUMENTATION REQUIRED: Document when the preferred biologic product or biosimilar was tried and the length of the trial period. Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem

Drug and Biologic Coverage Criteria

caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache).]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery, treatment of an infection or adverse event mitigation, causing temporary discontinuation
AND
2. Documented clinically significant improvements in the disease state, stability on the medication, or lack of disease progression
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of therapy: 6 months or maximum duration per FDA label or NCCN guideline or consortium, whichever is shorter

PRESCRIBER REQUIREMENTS:

Must be prescribed by, or in conjunction with, an oncologist, hematologist, or other specialist treating cancer

AGE RESTRICTIONS:

Must be prescribed within FDA or compendia supported labeled age maximums or minimums

QUANTITY:

FDA-labeled, NCCN, NCI, or AHFS supported dosing regimens or dosing schedules will be evaluated for approval.

PLACE OF ADMINISTRATION:

N/A

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Variable per drug

DRUG CLASS:

Antineoplastic

FDA-APPROVED USES:

Please refer to product package prescribing information

COMPENDIAL APPROVED OFF-LABELED USES:

Please see individual compendia monographs

APPENDIX

APPENDIX:

A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product.

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Drug and Biologic Coverage Criteria

Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.¹ As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating Preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising member satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products>. Accessed October 8, 2019.

Starter Fill Program (Split Fill Program)

Molina Healthcare has identified medications which have a high incidence of adverse effects, frequent dose modifications, or poor tolerability. For member's that are new utilizers of the medication, the program limits the dispensing of the medication to a 14-day supply, until the member has received a cumulative 90-day supply of the medication. This program also monitors to ensure that members fill a cumulative 90-day supply in rolling 6-month periods. If the member's medication adherence falls below this threshold, the member is limited to a 14-day supply until the 90-day cumulative supply is met. This program is intended to reduce medication waste, while also improving member care and medication adherence. Medications identified for this program must also be appropriate for dispensing in a 14-day supply. Medications that must be dispensed in the manufacturer's packaging (i.e., labeled "Dispense in original bottle") would not be eligible for this program.

DRUG	GPI	NEW program x 3 months
Afinitor (everolimus)	215325300003**	14 days per fill
Ayvakit (avapritinib)	214900090003**	15 days per fill
Balversa (erdafitinib)	215322250003**	15 days per fill
Bosulif (bosutinib)	215340120003**	15 days per fill
Brukina (zanubrutinib)	215321950001**	15 days per fill
Cabometyx (cabozantinib)	215340131003**	15 days per fill
Calquence (acalabrutinib)	21532103*****	15 days per fill
Daurismo (glasdegib)	213700303003**	14 days per fill
Erivedge (vismodegib)	21370070000120	14 days per fill
Exkivity (mobocertinib)	213600506001**	15 days per fill
Gavreto (pralsetinib)	215357500001**	15 days per fill
Gleevec (imatinib)	215340351003**	15 days per fill
Inlyta (axitinib)	215340080003**	15 days per fill
Inrebic (fedratinib)	215375202001**	15 days per fill
Iressa (gefitinib)	21534030000320	15 days per fill
Lorbrena (lorlatinib)	215305560003**	15 days per fill
Lumakras (sotorasib)	215324800003**	15 days per fill
Lysodren (mitotane)	214022500003**	15 days per fill
Nerlynx (neratinib)	21534058100320	15 days per fill
Nexavar (sorafenib)	21533060400320	15 days per fill
Odomzo (sonidegib)	21370060200120	15 days per fill
Retevmo (selpercatinib)	215357790001**	15 days per fill
Rozlytrek (entrectinib)	2153382000****	15 days per fill
Rubraca (rucaparib)	215355702003**	15 days per fill
Sprycel (dasatinib)	215340200003**	15 days per fill
Tagrisso (osimertinib)	215340652003**	15 days per fill
Talzenna (talazoparib)	215355804001**	15 days per fill
Tarceva (erlotinib)	215340251003**	15 days per fill
Targetin (bexarotene)	21708220000120	15 days per fill
Tazverik (tazemetostat)	215336752003**	15 days per fill
Tepmetko (tepotinib)	21533073100320	15 days per fill
Tibsovo (ivosidenib)	215349400003**	15 days per fill
Uknoniq (umbralisib)	21533080400320	15 days per fill

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Vitrakvi (larotrectinib)	2153383520****	15 days per fill
Vizimpro (dacomitinib)	215340190003**	15 days per fill
Votrient (pazopanib)	21534070100320	15 days per fill
Welireg (belzutifan)	214210200003**	15 days per fill
Xalkori (crizotinib)	215340150001**	15 days per fill
Xtandi (enzalutamide)	21402430000120	15 days per fill
Yonsa (abiraterone)	214060102003**	15 days per fill
Zejula (niraparib)	2153555020****	15 days per fill
Zolinza (vorinostat)	21531575000120	15 days per fill
Zykadia (ceritinib)	21534014000130	15 days per fill
Zytiga (abiraterone acetate)	214060102003**	15 days per fill

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Imbruvica (ibrutinib) Accelerated Approval Withdrawal

On April 6, 2023, Janssen Pharmaceuticals announced the withdrawal of indications for Imbruvica for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, and for the treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. This decision was made in consultation with the U.S. Food and Drug Administration (FDA), consistent with FDA procedural guidance on accelerated approvals. This decision does not affect any other approved indications for Imbruvica. NCCN clinical practice guidelines for B-Cell Lymphomas still lists ibrutinib as other recommended regimen for second line or subsequent therapy for MCL and MZL and notes “Head-to-head clinical trials in other B-cell malignancies have demonstrated a more favorable toxicity profile for acalabrutinib and zanubrutinib compared to ibrutinib without compromising efficacy.” The NCCN guidelines were last updated on February 8, 2023 and this timeline should be considered during review determinations for Imbruvica for these withdrawn indications.

The NCCN 6.2023 version of B-Cell Lymphomas has kept this recommendation after the withdrawal. For both MCL (MS-88) and MZL (MS-65), ibrutinib has been moved from a preferred regimen to other recommended regimen.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of antineoplastic agents are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy. See individual drug monographs for contraindications.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
Various	Physician Administered Medication List

Drug and Biologic Coverage Criteria

AVAILABLE DOSAGE FORMS:

Abraxane (paclitaxel protein-bound)
Actimmune (interferon gamma-1b)
Adriamycin (doxorubicin)
Adrucil (fluorouracil)
Afinitor (everolimus)
Akeega (niraparib)
Alecensa (alectinib)
Alferon N (interferon alfa-n3)
Alimta (pemetrexed disodium)
Aliqopa (copanlisib)
Alkeran (melphalan)
Alunbrig (brigatinib)
Alymsys (bevacizumab)
Aromasin (exemestane)
Arranon (nelarabine)
Arzerra (ofatumumab)
Asparlas (calaspargase pegol-mknl)
Augtyro (repotrectinib)
Avastin (bevacizumab)
Ayvakit (avapritinib)
Azedra (iobenguane I 131)*
Balversa (erdafitinib)
Bavencio (avelumab)
Beleodaq (belinostat)
Belrapzo (bendamustine)
Bendeka (bendamustine)
Besponsa (inotuzumab ozogamicin)
Besremi (ropeginterferon alfa-2b)
Bicnu (carmustine)
Blenoxane (bleomycin sulfate)
Blenrep (belantamab)*
Blincyto (blinatumomab)*
Bosulif (bosutinib)
Braftovi (encorafenib)
Brukinsa (zanubrutinib)
Busulfex (busulfan)
Cabometyx (cabozantinib)*
Calquence (acalbrutinib)
Camptosar (irinotecan)
Caprelsa (vandetanib)
Casodex (bicalutamide)
Cerubidine (daunorubicin)
Clolar (clofarabine)
Columvi (glofitamab)
Cometriq (cabozantinib)
Copiktra (duvelisib)*
Cosmegen (dactinomycin)
Cotellic (cobimetinib)
Cyramza (ramucirumab)*
Cytosar-U (cytarabine)
Cytosan (cyclophosphamide)
Dacarbazine
Dacogen (decitabine)
Danyelza (naxitamab-gqgk)*
Darzalex (daratumumab)
Daurismo (glasdegib)*
Doxil (doxorubicin)
Elahere (mirvetuximab)
Elitek (rasburicase)
Ellence (epirubicin hcl)
Elrexio (elranatamab)
Elzonris (Tagraxofusp-erzs)
Emcyt (estramustine)
Empliciti (elotuzumab)*
Enhertu (fam-trastuzumab deruxtecan-nxki)
Epkinly (epcoritamab)
Erbitux (cetuximab)
Erivedge (vismodegib)
Erleada (apalutamide)
Erwinase (asparaginase)
Erwinaze (asparaginase)
Ethyol (amifostine)
Etopophos (etoposide phosphate)
Evomela (melphalan)
Exkivity (mobocertinib)
Fareston (toremifene)
Farydak (panbinostat)
Faslodex (fulvestrant)
Femara (letrozole)
Firmagon (degarelix)
Floxuridine
Fludara (fludarabine)
Folotyn (pralatrexate)
Fruzaqla (fruquintinib)
Fotivda (Tivozanib)
Fusilev (levoleucovorin)
Fyarro (Sirolimus Protein-Bound)
Gavreto (pralsetinib)*
Gazyva (obinutuzumab)
Gemzar (gemcitabine)
Gilotrif (afatinib)*
Gleevec (imatinib)
Gleostine (lomustine)
Gliadel Wafer (carmustine implant)
Halaven (eribulin mesylate)
Herceptin (trastuzumab) Herxuma (trastuzumab-pkrb)
Hycamtin (topotecan)
Hydrea (hydroxyurea)
Hydroxyprogesterone caproate
Ibrance (palbociclib)
Iclusig (ponatinib)
Idamycin (idarubicin)
Idhifa (enasidenib)
Ifex (ifosfamide)
Imbruvica (ibrutinib)
Imfinzi (durvalumab)*
Imjudo (tremelimumab)
Imlygic (talimogene laherparepvec)
Infugem (gemcitabine)
Inqovi (decitabine; cedazuridine)
Inlyta (axitinib)
Intron A (interferon alfa-2b)
Iressa (gefitinib)
Istodax (romidepsin)
Ixempra (ixabepilone)
Jaypirca (pirtobrutinib)
Jelmyto (mitomycin)
Jemperli (dostarlimab)
Jevtana (cabazitaxel)
Jylamvo (methotrexate)
Kadcyla (ado-trastuzumab emtansine)
Kanjinti (trastuzumab-anns)
Kepivance (palifermin)
Keytruda (pembrolizumab)*
Khapzory (levoleucovorin)
Kimmtrak (tebentafusp)
Kisqali (ribociclib)
Kisqali Femara (ribociclib, letrozole)
Krazati (adagrasib)
Kyprolis (carfilzomib)
Lartruvo (olaratumab)
Lenvima (lenvatinib)
Leucovorin
Leukeran (chlorambucil)
Leustatin (cladribine)
Libtayo (cemiplimab-rwlc)
Lipodox (doxorubicin)
Lonsurf (trifluridine/tipiracil)
Loqtorzi (toripalimab)
Lorbrena (lorlatinib)*
Lumakras (sotorasib)
Lumoxiti (moxetumomab)*
Lunsumio (mosunetuzumab)
Lynparza (olaparib)*
Lysodren (mitotane)
Lytgobi (futibatinib)
Margenza (margetuximab)
Marqibo (vincristine sulfate liposome)
Matulane (procarbazine)
Mekinist (trametinib)*
Mektovi (binimetinib)
Mesnex (mesna)
Mitosol (mitomycin)
Monjuvi (tafasitamab-cxix)*
Mutamycin (mitomycin)
Mvasi (bevacizumab-awwb)
Myleran (busulfan)
Mylotarg (gemtuzumab ozogamicin)
Navelbine (vinorelbine)
Nerlynx (neratinib)
Nexavar (sorafenib)
Nilandron (nilutamide)
Ninlaro (ixazomib) Nipent (pentostatin)
Novantrone (mitoxantrone)
Nubeqa (darolutamide)
Odomzo (sonidegib)
Ogivri (trastuzumab-dkst)
Ogsiveo (nirogacestat)
Oncaspar (pegaspargase)
Onivyde (irinotecan liposome)
Ontruzant (trastuzumab-dttb)
Onureg (azacytidine)
Opdivo (nivolumab)

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Opdualag (nivolumab-relatlimab)	Tafinlar (dabrafenib)*	Vegzelma (bevacizumab)
Orserdu (elacestrant)	Tagrisso (osimertinib)*	Velcade (bortezomib)
Pagcev (enfortumab vedotin)	Talvey (talquetamab)	Venclexta (venetoclax)
Pemazyre (pemigatinib)*	Talzenna (talazoparib)	Verzenio (abemaciclib)
Pemfexy (pemetrexed)	Tarceva (erlotinib)	Vesanoid (tretinoin)
Perjeta (pertuzumab)	Targretin (bexarotene)	Vidaza (azacitidine)
Phesgo (pertuzumab; trastuzumab;hyaluronidase)	Tasigna (nilotinib)	Vinblastine
Photofrin (porfimer sodium)	Taxol (paclitaxel)	Vincasar (vincristine)
Piqray (alpelisib)	Taxotere (docetaxel)	Vitrakvi (Larotrectinib)
Platinol (cisplatin)	Tazverik (tazemetostat)	Vivimusta (bendamustine)
Polivy (polatuzumab vedotin)	Tecentriq (atezolizumab)*	Vizimpro (dacomitinib)
Pomalyst (pomalidomide)	Tecvayli (teclistamab)	Votrient (pazopanib)
Portrazza (necitumamab)	Temodar (temozolomide)	Vumon (teniposide)
Poteligeo (mogamulizumab)*	Tepadina (thiotepa)	Vyxeos (daunorubicin-cytarabine)
Proleukin (aldesleukin)	Tepmetko (tepotinib)	Welireg (belzutifan)
Purinethol (mercaptapurine)	Thalomid (thalidomide)	Xalkori (crizotinib)
Purixan (mercaptapurine)	Tibovo (ivosidenib)*	Xatmep (methotrexate)
Qinlock (ripretinib)	Tice BCG	Xeloda (capecitabine)
Quadramet (samarium SM 153 lexidronam)	Tivdak (tisotumab vedotin)	Xofigo (radium 223)
Retevmo (selpercatinib)	Toposar (etoposide)	Xospata (gilteritinib)*
Revlimid (lenalidomide)*	Torisel (temsirolimus)	Xpovio (selinexor)*
Rezlidhia (olutasidenib)	Totect (dexrazoxane)	Xtandi (enzalutamide)
Rozlytrek (entrectinib)	Trazimera (trastuzumab-qyyp)	Yervoy (ipilimumab)
Rubraca (rucaparib)*	Treanda (bendamustine)	Yondelis (trabectedin)
Rybrevant (amivantamab)	Trelstar (triptorelin pamoate)	Yonsa (abirateron acetate)
Rydapt (midostaurin)	Trexall (methotrexate)	Zaltrap (aflibercept)
Rylaze (asparaginase)	Trisenox (arsenic trioxide)	Zanosar (streptozocin)
Sarclisa (isatuximab)	Trodelyv (Sacituzumab)	Zejula (niraparib)
Scemblix (asciminib)	Truqap (capivasertib)	Zelboraf (vemurafenib)
Soltamox (tamoxifen)	Truseltiq (infigratinib)	Zepzelca (lurbinectedin)
Sprycel (dasatinib)*	Tukysa (tucatinib)	Zevalin (ibritumomab tiuxetan)
Stivarga (regorafenib)	Turalio (pexidartinib)*	Zinecard (dexrazoxane)
Sutent (sunitinib malate)	Tykerb (lapatinib)	Zirabev (bevacizumab-bvzr)
Sylatron (peginterferon alfa-2b)	Ukoniq (umbralisib)*	Zolinza (vorinostat)
Sylvant (siltuximab)	Unituxin (dinutuximab)	Zydelig (idelalisib)
Synribo (omacetaxine mepesuccinate)	Uvadex (methoxsalen)	Zykadia (ceritinib)
Tabloid (thiguanine)	Valstar (valrubicin)	Zynlonta (loncastuximab tesirine)
Tabrecta (capmatinib)*	Vanflyta (quizartinib)	Zynyz (retifanlimab)
	Vantas (histrelin)	Zytiga (abiraterone acetate)
	Vectibix (panitumumab)	

*High risk alert

REFERENCES

NA

Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Place of Administration Appendix Background Available Dosage Forms	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Place of Administration Appendix Contraindications/Exclusions/Discontinuation Available dosage Forms	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file