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Prior Authorization Proposal: Oncology Agents

Purpose for the Proposal:
The purpose of the prior authorization (PA) proposal is to ensure medically appropriate use of antineoplastic agents, both those recently approved and those approved by the United States Food and Drug Administration (FDA) in the future.

Background:
Oncology is a rapidly growing area of drug development. In 2017, the FDA approved 12 novel drug therapies as well as 2 gene therapies for oncology.[1-3] In 2018 and 2019, there were 27 novel agents FDA-approved for oncology indications. Additional indications beyond the first FDA approval are often studied in clinical trials for these agents as well and many obtain subsequent new or expanded indication approvals. According to Oregon Administrative Rule 410-120-1200(2)(i), the Division of Medical Assistance Programs will not cover services or items considered experimental or investigational, including clinical trials and demonstration projects, or services that deviate from acceptable and customary standards of medical practice or for which there is insufficient outcome data to indicate efficacy.[4] Off-label use beyond FDA-approved indications may be considered when supported by Centers for Medicare and Medicaid Services (CMS) compendia. One of the most commonly used guidelines for oncology is the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®), which are supported by CMS as a compendia for "use in the determination of a 'medically-accepted indication' of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen".[5,6] NCCN guidelines strongly encourage enrollment in clinical trials for any patient with cancer in order to get the best therapy management. While the Oregon Health Authority is statutorily unable to cover experimental or investigational treatments, access to clinical trials is supported, and appropriate standard of care for patients enrolled in a clinical trial would be covered.

In addition, the Health Evidence Review Commission provides the following guidance for patient-centered care of advanced cancer.[7]

> GUIDELINE NOTE 12, PATIENT-CENTERED CARE OF ADVANCED CANCER
> Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall heath, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).
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> Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with:
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> A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
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> B) A continued decline in spite of best available therapy with a non-reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.

Examples include:

A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life.
B) Surgical decompression for malignant bowel obstruction. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma)
C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

Both oral and parenteral oncology drugs are typically studied in multiple indications, may have safety concerns, and are generally of high cost. Therefore, a broad PA policy that requires use to align with FDA-approved or NCCN-supported indications and HERC guideline note 12 would ensure appropriate use of these agents. Current policies implemented by other state Medicaid agencies and 2 Coordinated Care Organizations were considered during policy development. Feedback was also solicited from 2 oncology providers and HERC staff to aid in the development of this proposal.

Proposal and Methods:

A new Antineoplastics preferred drug list (PDL) class was created and all applicable agents (whether previously in a PDL class or not) were added to the class.

This proposal to require PA encompasses any new start of an antineoplastic agent approved within the past 12 years. Drugs with an original FDA-approval date prior to January 2008, or subsequently approved new formulations of these older agents, are exempted from this criteria given the increased clinical experience with these agents.

The CMS Approval Date and National Drug Data File (NDDF) Add Date were utilized to identify antineoplastic drugs by unique generic name with a date for either field greater than or equal to 1/1/2008 for agents proposed to require PA. Any unique generic antineoplastic agents with any formulation identified with those parameters prior to 1/1/2008 are proposed to not require PA. A list of the medications proposed to require PA (n=85 unique generic name drugs) is provided in the proposed PA (**Appendix 1**) while the medications proposed to not require PA (n=108 unique generic name drugs) is provided in **Appendix 2**. The PA applies to pharmacy or physician administered drugs given in an outpatient setting and is not intended to apply to emergency or inpatient services.

Recommendation:

- Implement PA criteria to ensure medically appropriate use for all drugs in the Antineoplastics PDL class originally approved by the FDA on 1/1/2008 or later (**Appendix 1**).
- In future, any antineoplastic new molecular entities and new formulations of drugs that already require PA will be added to the Antineoplastics PDL class upon approval by the Food and Drug Administration (FDA), and PA criteria will be updated to incorporate these new agents at subsequent P&T meetings.

References:

1. Novel Drug Approvals for 2017. United States Food and Drug Administration Website. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm. Updated February 2, 2018. Accessed August 20, 2018.
2. FDA approval brings first gene therapy to the United States. United States Food and Drug Administration Website. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm574058.htm. Updated March 26, 2018. Accessed August 20, 2018.
3. FDA approves CAR-T cell therapy to treat adults with certain types of large B-cell lymphoma. United States Food and Drug Administration Website. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm581216.htm. Updated March 21, 2018. Accessed August 20, 2018.
4. Oregon Health Authority. Health Systems Division Medical Assistance Programs - Chapter 410. Oregon Secretary of State. https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=83120. Accessed December 18, 2018.
5. NCCN Compendium Revision Request. CMS.gov. Available from: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=14&mcdtypename=Compendia&MCDIndexType=6&bc=AgAEAAAAAAAA&. Accessed August 20, 2018.
6. Compendia. CMS.gov. Available from: https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDId=14&mcdtypename=Compendia&MCDIndexType=6&bc=AgAEAAAAAAAA&. Accessed August 20, 2018.
7. Prioritized List of Health Services. Health Evidence Review Commission. Oregon Health Authority. Available from: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx. Accessed December 18, 2018.

Appendix 1: Proposed Prior Authorization Criteria

Oncology Agents

Goal(s):

- To ensure appropriate use for oncology medications based on FDA-approved and compendia-recommended (i.e., National Comprehensive Cancer Network® [NCCN]) indications.

Length of Authorization:

- Up to 1 year

Requires PA:

- Initiation of therapy for drugs listed in **Table 1** (applies to both pharmacy and physician administered claims). This does not apply to oncologic emergencies administered in an emergency department or during inpatient admission to a hospital.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of an oncologic emergency (e.g., superior vena cava syndrome [ICD-10 I87.1] or spinal cord compression [ICD-10 G95.20]) administered in the emergency department?	**Yes:** Approve for length of therapy or 12 months, whichever is less.	**No:** Go to #3
3. Is the request for any continuation of therapy?	**Yes:** Approve for length of therapy or 12 months, whichever is less.	**No**: Go to #4
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the indication FDA-approved for the requested drug? Note: This includes all information required in the FDA-approved indication, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy.	**Yes**: Pass to RPh. Approve for length of therapy or 12 months, whichever is less.	**No:** Go to #6

Approval Criteria		
6. Is the indication recommended by National Comprehensive Cancer Network (NCCN) Guidelines® for the requested drug? Note: This includes all information required in the NCCN recommendation, including but not limited to the following as applicable: diagnosis, stage of cancer, biomarkers, place in therapy, and use as monotherapy or combination therapy.	**Yes:** Pass to RPh. Approve for length of therapy or 12 months, whichever is less.	**No:** Go to #7
7. Is there documentation based on chart notes that the patient is enrolled in a clinical trial to evaluate efficacy or safety of the requested drug?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: The Oregon Health Authority is statutorily unable to cover experimental or investigational therapies.	**No:** Go to #8
8. Is the request for a rare cancer which is not addressed by National Comprehensive Cancer Network (NCCN) Guidelines® and which has no FDA approved treatment options?	**Yes:** Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. All other diagnoses must be evaluated for evidence of clinical benefit. The prescriber must provide the following documentation: • medical literature or guidelines supporting use for the condition, • clinical chart notes documenting medical necessity, and • documented discussion with the patient about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. RPh may use clinical judgement to approve drug for length of treatment or deny request based on documentation provided by prescriber. If new evidence is provided by the prescriber, please forward request to Oregon DMAP for consideration and potential modification of current PA criteria.		

Table 1. Oncology agents which apply to this policy

Generic Name	Brand Name
abemaciclib	VERZENIO
abiraterone acet,submicronized	YONSA
abiraterone acetate	ZYTIGA
acalabrutinib	CALQUENCE
ado-trastuzumab emtansine	KADCYLA
afatinib dimaleate	GILOTRIF
alectinib HCl	ALECENSA
Alpelisib	PIQRAY
apalutamide	ERLEADA
asparaginase (Erwinia chrysan)	ERWINAZE
atezolizumab	TECENTRIQ
avapritinib	AYVAKIT
avelumab	BAVENCIO
axicabtagene ciloleucel	YESCARTA
axitinib	INLYTA
belinostat	BELEODAQ
bendamustine HCl	BENDAMUSTINE HCL
bendamustine HCl	BENDEKA
bendamustine HCl	TREANDA
binimetinib	MEKTOVI
blinatumomab	BLINCYTO
bosutinib	BOSULIF
brentuximab vedotin	ADCETRIS
brigatinib	ALUNBRIG
cabazitaxel	JEVTANA
cabozantinib s-malate	CABOMETYX
cabozantinib s-malate	COMETRIQ
Calaspargase pegol-mknl	ASPARLAS
carfilzomib	KYPROLIS
cemiplimab-rwlc	LIBTAYO
ceritinib	ZYKADIA
cobimetinib fumarate	COTELLIC
copanlisib di-HCl	ALIQOPA
crizotinib	XALKORI
dabrafenib mesylate	TAFINLAR

dacomitinib	VIZIMPRO
daratumumab	DARZALEX
Darolutamide	NUBEQA
degarelix acetate	FIRMAGON
dinutuximab	UNITUXIN
durvalumab	IMFINZI
duvelisib	COPIKTRA
elotuzumab	EMPLICITI
enasidenib mesylate	IDHIFA
encorafenib	BRAFTOVI
Enfortumab vedotin-ejfv	PADCEV
Entrectinib	ROZLYTREK
enzalutamide	XTANDI
erdafitinib	BALVERSA
eribulin mesylate	HALAVEN
everolimus	AFINITOR
everolimus	AFINITOR DISPERZ
fam-trastuzumab deruxtecan-nxki	ENHERTU
fedratinib	INREBIC
gilteritinib	XOSPATA
glasdegib	DAURISMO
ibrutinib	IMBRUVICA
idelalisib	ZYDELIG
ingenol mebutate	PICATO
inotuzumab ozogamicin	BESPONSA
ipilimumab	YERVOY
Isatuximab	SARCLISA
ivosidenib	TIBSOVO
ixazomib citrate	NINLARO
larotrectinib	VITRAKVI
lenvatinib mesylate	LENVIMA
lorlatinib	LORBRENA
Lutetium Lu 177 dotate	LUTATHERA
midostaurin	RYDAPT
moxetumomab pasudotox-tdfk	LUMOXITI
necitumumab	PORTRAZZA
neratinib maleate	NERLYNX
niraparib tosylate	ZEJULA

nivolumab	OPDIVO
obinutuzumab	GAZYVA
ofatumumab	ARZERRA
olaparib	LYNPARZA
olaratumab	LARTRUVO
omacetaxine mepesuccinate	SYNRIBO
osimertinib mesylate	TAGRISSO
palbociclib	IBRANCE
panobinostat lactate	FARYDAK
pazopanib HCl	VOTRIENT
pembrolizumab	KEYTRUDA
pemigatinib	PEMAZYRE
pertuzumab	PERJETA
Pexidartinib	TURALIO
Polatuzumab vedotin-piiq	POLIVY
pomalidomide	POMALYST
ponatinib HCl	ICLUSIG
pralatrexate	FOLOTYN
ramucirumab	CYRAMZA
regorafenib	STIVARGA
ribociclib succinate	KISQALI
ribociclib succinate/letrozole	KISQALI FEMARA CO-PACK
romidepsin	ISTODAX
romidepsin	ROMIDEPSIN
rucaparib camsylate	RUBRACA
ruxolitinib phosphate	JAKAFI
Sacitizumab govitecan-hziy	TRODELVY
Selinexor	XPOVIO
siltuximab	SYLVANT
sipuleucel-T/lactated ringers	PROVENGE
sonidegib phosphate	ODOMZO
Tagraxofusp-erzs	ELZONRIS
talazoparib	TALZENNA
talimogene laherparepvec	IMLYGIC
Tazemetostat	TAZVERIK
tisagenlecleucel	KYMRIAH
trabectedin	YONDELIS
trametinib dimethyl sulfoxide	MEKINIST

trifluridine/tipiracil HCl	LONSURF
Tucatinib	TUKYSA
vandetanib	CAPRELSA
vandetanib	VANDETANIB
vemurafenib	ZELBORAF
venetoclax	VENCLEXTA
venetoclax	VENCLEXTA STARTING PACK
vismodegib	ERIVEDGE
zanubrutinib	BRUKINSA
ziv-aflibercept	ZALTRAP

P&T/DUR Review: 6/2020 (JP)
Implementation: 10/1/20

Appendix 2. Antineoplastic Agents Proposed to Not Require Prior Authorization

Generic Name	Brand Name
aldesleukin	PROLEUKIN
alemtuzumab	CAMPATH
alitretinoin	PANRETIN
altretamine	HEXALEN
aminolevulinic acid HCl	AMELUZ
aminolevulinic acid HCl	LEVULAN
anastrozole	ANASTROZOLE
anastrozole	ARIMIDEX
arsenic trioxide	TRISENOX
azacitidine	AZACITIDINE
azacitidine	VIDAZA
BCG live	BCG (TICE STRAIN)
BCG live	THERACYS
bexarotene	BEXAROTENE
bexarotene	TARGRETIN
bicalutamide	BICALUTAMIDE
bicalutamide	CASODEX
bleomycin sulfate	BLEO 15K
bleomycin sulfate	BLEOMYCIN SULFATE
bortezomib	BORTEZOMIB
bortezomib	VELCADE
busulfan	BUSULFAN
busulfan	BUSULFEX
busulfan	MYLERAN
capecitabine	CAPECITABINE
capecitabine	XELODA
carboplatin	CARBOPLATIN
carmustine	BICNU
carmustine in polifeprosan 20	GLIADEL
cetuximab	ERBITUX
chlorambucil	LEUKERAN
cisplatin	CISPLATIN
cladribine	CLADRIBINE
clofarabine	CLOFARABINE
clofarabine	CLOLAR

Generic Name	Brand Name
cyclophosphamide	CYCLOPHOSPHAMIDE
cyclophosphamide	NEOSAR
cytarabine	CYTARABINE
cytarabine/PF	CYTARABINE
dacarbazine	DACARBAZINE
dactinomycin	COSMEGEN
dactinomycin	DACTINOMYCIN
dasatinib	SPRYCEL
daunorubicin HCl	DAUNORUBICIN HCL
daunorubicin/cytarabine lipos	VYXEOS
decitabine	DACOGEN
decitabine	DECITABINE
docetaxel	DOCEFREZ
docetaxel	DOCETAXEL
docetaxel	TAXOTERE
doxorubicin HCl	ADRIAMYCIN
doxorubicin HCl	ADRIAMYCIN RDF
doxorubicin HCl	DOXORUBICIN HCL
doxorubicin HCl	RUBEX
doxorubicin HCl peg-liposomal	DOXIL
doxorubicin HCl peg-liposomal	DOXORUBICIN HCL LIPOSOME
doxorubicin HCl peg-liposomal	LIPODOX
doxorubicin HCl peg-liposomal	LIPODOX 50
epirubicin HCl	ELLENCE
epirubicin HCl	EPIRUBICIN HCL
erlotinib HCl	TARCEVA
estramustine phosphate sodium	EMCYT
etoposide	ETOPOSIDE
etoposide	TOPOSAR
etoposide phosphate	ETOPOPHOS
exemestane	AROMASIN
exemestane	EXEMESTANE
floxuridine	FLOXURIDINE
fludarabine phosphate	FLUDARABINE PHOSPHATE
fluorouracil	ADRUCIL

Generic Name	Brand Name
fluorouracil	CARAC
fluorouracil	EFUDEX
fluorouracil	FLUOROURACIL
fluorouracil	TOLAK
flutamide	FLUTAMIDE
fulvestrant	FASLODEX
gefitinib	IRESSA
gemcitabine HCl	GEMCITABINE HCL
gemcitabine HCl	GEMZAR
hydroxyurea	HYDREA
hydroxyurea	HYDROXYUREA
idarubicin HCl	IDAMYCIN PFS
idarubicin HCl	IDARUBICIN HCL
ifosfamide	IFEX
ifosfamide	IFOSFAMIDE
ifosfamide/mesna	IFOSFAMIDE-MESNA
imatinib mesylate	GLEEVEC
imatinib mesylate	IMATINIB MESYLATE
interferon alfa-2b,recomb.	INTRON A
interferon gamma-1b,recomb.	ACTIMMUNE
irinotecan HCl	CAMPTOSAR
irinotecan HCl	IRINOTECAN HCL
irinotecan liposomal	ONIVYDE
ixabepilone	IXEMPRA
kit Y-90/ibritumomab/h.albumin	ZEVALIN
lapatinib ditosylate	TYKERB
lenalidomide	REVLIMID
letrozole	FEMARA
letrozole	LETROZOLE
lomustine	GLEOSTINE
mechlorethamine HCl	MUSTARGEN
mechlorethamine HCl	VALCHLOR
megestrol acetate	MEGESTROL ACETATE
melphalan	ALKERAN
melphalan	MELPHALAN
melphalan HCl	ALKERAN
melphalan HCl	MELPHALAN HCL

Generic Name	Brand Name
melphalan HCl/betadex sbes	EVOMELA
mercaptopurine	MERCAPTOPURINE
mercaptopurine	PURIXAN
methotrexate	XATMEP
methotrexate sodium	METHOTREXATE
methotrexate sodium	TREXALL
methotrexate sodium/PF	METHOTREXATE
methotrexate sodium/PF	METHOTREXATE SODIUM
mitomycin	MITOMYCIN
mitomycin	MUTAMYCIN
mitotane	LYSODREN
mitoxantrone HCl	MITOXANTRONE HCL
nelarabine	ARRANON
nilotinib HCl	TASIGNA
nilutamide	NILANDRON
nilutamide	NILUTAMIDE
oxaliplatin	OXALIPLATIN
paclitaxel	PACLITAXEL
paclitaxel protein-bound	ABRAXANE
panitumumab	VECTIBIX
pegaspargase	ONCASPAR
peginterferon alfa-2b	SYLATRON
pemetrexed disodium	ALIMTA
pentostatin	NIPENT
plicamycin	MITHRACIN
procarbazine HCl	MATULANE
rituximab/hyaluronidase,human	RITUXAN HYCELA
sorafenib tosylate	NEXAVAR
streptozocin	ZANOSAR
sunitinib malate	SUTENT
tamoxifen citrate	SOLTAMOX
tamoxifen citrate	TAMOXIFEN CITRATE
temozolomide	TEMODAR
temozolomide	TEMOZOLOMIDE
temsirolimus	TORISEL
teniposide	TENIPOSIDE
thioguanine	TABLOID

Generic Name	Brand Name
thiotepa	TEPADINA
thiotepa	THIOTEPA
topotecan HCl	HYCAMTIN
topotecan HCl	TOPOTECAN HCL
toremifene citrate	FARESTON
trastuzumab	HERCEPTIN
tretinoin	TRETINOIN
valrubicin	VALSTAR

Generic Name	Brand Name
vinblastine sulfate	VINBLASTINE SULFATE
vincristine sulfate	VINCASAR PFS
vincristine sulfate	VINCRISTINE SULFATE
vincristine sulfate liposomal	MARQIBO
vinorelbine tartrate	NAVELBINE
vinorelbine tartrate	VINORELBINE TARTRATE
vorinostat	ZOLINZA