

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Colony Stimulating Factors

Overrides	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Fulphila (pegflgrastim-jmdb)	May be subject to quantity limit
Granix (tbo-filgrastim)	N/A
Leukine (sargramotim)	N/A
Neulasta (pegfilgrastim)	May be subject to quantity limit
Neupogen (filgrastim)	N/A
Nivestym (filgrastim-aafi)	N/A
Udenyca (pegfilgrastim-cbqv)	May be subject to quantity limit
Zarxio (filgrastim-sndz)	N/A
Ziextenzo (pegfilgrastim-bmez)	May be subject to quantity limit

APPROVAL CRITERIA

- I. *In addition to criteria outlined below, requests for Granix, Leukine, Neupogen, Nivestym, must also meet the following criteria:

- A. Individual has had a trial and inadequate response or intolerance to Zarxio; **OR**
- B. Zarxio is not FDA-approved for the prescribed indication and Granix, Leukine, Neupogen or Nivestym is.

**Step Therapy does not apply to Florida Healthy Kids*

- II. Requests for filgrastim (Neupogen), filgrastim-aafi (Nivestym), or filgrastim-sndz (Zarxio) may be approved if the following criteria are met:

- A. Individual with nonmyeloid malignancy is using for primary prophylaxis of Febrile Neutropenia (FN); **AND**
- B. Individual has a risk of FN of 20% or greater based on chemotherapy regimen (see Appendix, Table 1);

OR

- C. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**
- D. Individual's risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy regimen (see Appendix, Table 1) and individual has any risk factors for:
 - 1. Age greater than 65 years (Lyman 2014; Aagaard 2018); **OR**

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2. Poor performance status (Eastern Cooperative Oncology Group 3 or 4) or HIV infection (in particular, those with low CD4 counts ($\leq 450/\mu\text{L}$) but chemotherapy still indicated) (Lyman 2014); **OR**
3. Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015); **OR**
4. Bone marrow involvement by tumor producing cytopenias (Lyman 2014); **OR**
5. Persistent neutropenia (absolute neutrophil count [ANC] less than 1500mm^3) (Lyman 2014); **OR**
6. Poor renal function (glomerular filtration rate [GFR] less than $60\text{mL}/\text{min}$) (Lyman 2014; Aagaard 2018); **OR**
7. Liver dysfunction (liver function tests at least 2X upper limit of normal or bilirubin $> 2.0\text{ mg}/\text{dL}$) (Lyman 2014; Aagaard 2018); **OR**
8. Recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc.) (Lyman 2014; Aagaard 2018); **OR**
9. History of active infection within previous 60 days (Lyman 2014; Aagaard 2018); **OR**
10. Current open wound and chemotherapy cannot be delayed (Lyman 2014; Aagaard 2018);

OR

- E. Individual with nonmyeloid malignancy is using for secondary prophylaxis of FN; **AND**
- F. Individual has experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome (NCCN 2A);

OR

- G. Individual is using as adjunctive treatment for FN (NCCN 2A); **AND**
- H. Individual has been on prophylactic therapy with filgrastim;
OR
- I. Individual has not received prophylactic therapy with granulocyte colony stimulating factor (NCCN Guidelines Myeloid Growth Factors); **AND**
- J. Individual has a high risk for infection-associated complications as demonstrated by any of the following (NCCN 2A):
1. Expected prolonged (greater than 10 days) and profound (less than $0.1 \times 10^9/\text{L}$) neutropenia; **OR**
 2. Age greater than 65 years; **OR**
 3. Pneumonia or other clinically documented infections; **OR**
 4. Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
 5. Invasive fungal infection; **OR**
 6. Prior episode of febrile neutropenia; **OR**
 7. Hospitalized at the time of the development of fever;

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OR

- K. Individual is 18 years of age or older and has a diagnosis of acute myeloid leukemia (AML); **AND**
- L. Individual is using shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML;

OR

- M. Individual has a diagnosis of hairy cell leukemia with severe neutropenia (AHFS, NCCN Guidelines Hairy Cell Leukemia);

OR

- N. Individual has a diagnosis of myelodysplastic syndromes (MDS) (NCCN 2A); **AND**
- O. Individual has severe neutropenia (ANC less than or equal to 500 mm³) or experiencing recurrent infection or resistant infections;

OR

- P. Individual is receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer (ASCO Smith 2015);

OR

- Q. Individual is using for chronic administration to reduce the incidence and duration of sequelae of neutropenia (for example, fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia;

OR

- R. Individual is using for the treatment of (non-chemotherapy) drug-induced neutropenia (AHFS);

OR

- S. Individual is less than 21 years of age and has a diagnosis of glycogen storage disease type 1b; **AND**
- T. Individual is using for the treatment of low neutrophil counts (AHFS);

OR

- U. Individual is using for the treatment for neutropenia associated with human immunodeficiency virus infection and antiretroviral therapy (AHFS);

OR

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V. Individual is using after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome);

OR

W. Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed (NCCN 2A);

OR

X. Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT);

OR

Y. Individual is using as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant (DrugPoints B IIa);

OR

Z. Individual is using to reduce the duration of neutropenia and neutropenia related clinical sequelae in those with nonmyeloid malignancies undergoing myeloblastic chemotherapy followed by bone marrow transplant (BMT).

III. Requests for pegfilgrastim (Neulasta), pegfilgrastim-jmdb (Fulphila), pegfilgrastim-cbqv (Udenyca), or pegfilgrastim-bmez (Ziextenzo) or may be approved if the following criteria are met:

- A. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**
- B. Individual has a risk of FN of 20% or greater based on chemotherapy regimen (see Appendix, Table1);

OR

- C. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**
- D. Individual's risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy regimen (see Appendix, Table 1) and individual has any of the following risk factors for FN:
 1. Age greater than 65 years (Lyman 2014; Aagaard 2018); **OR**
 2. Poor performance status (Eastern Cooperative Oncology Group 3 or 4) or HIV infection (in particular, those with low CD4 counts ($\leq 450/\mu\text{L}$) but chemotherapy still indicated) (Lyman 2014); **OR**

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3. Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015); **OR**
4. Bone marrow involvement by tumor producing cytopenias (Lyman 2014); **OR**
5. Persistent neutropenia (absolute neutrophil count [ANC] less than 1500mm³) (Lyman 2014); **OR**
6. Poor renal function (glomerular filtration rate [GFR] less than 60mL/min) (Lyman 2014; Aagaard 2018); **OR**
7. Liver dysfunction (liver function tests at least 2X upper limit of normal or bilirubin > 2.0 mg/dL) (Lyman 2014; Aagaard 20218); **OR**
8. Recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc.) (Lyman 2014; Aagaard 2018); **OR**
9. History of active infection within previous 60 days(Lyman 2014; Aagaard 2018); **OR**
10. Current open wound and chemotherapy cannot be delayed (Lyman 2014; Aagaard 2018);

OR

E. Individual with nonmyeloid malignancy is using for secondary prophylaxis of FN;

AND

F. Individual has experienced a neutropenic complication from a prior cycle of chemotherapy (for which prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome (NCCN 2A);

OR

G. Individual is using as adjunctive treatment for FN; **AND**

H. Individual has not received prophylactic therapy with pegfilgrastim (NCCN 2A);

AND

- I. Individual has a high risk for infection-associated complications as demonstrated by any of the following:
1. Expected prolonged (greater than 10 days) and profound (less than 0.1 x 10⁹/L) neutropenia; **OR**
 2. Age greater than 65 years; **OR**
 3. Pneumonia or other clinically documented infections; **OR**
 4. Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
 5. Invasive fungal infection; **OR**
 6. Prior episode of febrile neutropenia; **OR**
 7. Hospitalized at the time of the development of fever;

OR

J. Individual is receiving dose dense therapy (treatment given more frequently, such

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as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer (ASCO Smith 2015);

OR

K. Individual is using after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome);

OR

L. Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed (NCCN 2A).

IV. Requests for sargramostim (Leukine) may be approved if the following criteria are met:

- A. Individual is using as adjunctive treatment for FN: **AND**
- B. Individual has not previously received prophylactic granulocyte colony-stimulating factors (NCCN 2A); **AND**
- C. Individual has a high risk for infection-associated complications as demonstrated by any of the following (NCCN 2A):
 1. Expected prolonged (greater than 10 days) and profound (less than $0.1 \times 10^9/L$) neutropenia; **OR**
 2. Age greater than 65 years; **OR**
 3. Pneumonia or other clinically documented infections; **OR**
 4. Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
 5. Invasive fungal infection; **OR**
 6. Prior episode of febrile neutropenia; **OR**
 7. Hospitalized at the time of the development of fever;

OR

D. Individual is receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer (ASCO Smith 2015);

OR

- E. Individual has a diagnosis of acute myeloid leukemia (AML); **AND**
- F. Individual is 55 years and older **AND**
- G. Individual is using shortly after the completion of induction or repeat induction of chemotherapy of AML;

OR

H. Individual has a diagnosis of myelodysplastic syndromes (MDS); **AND**

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Applicable	X	X	X	X	X	X	X

I. Individual has severe neutropenia (ANC less than or equal to 500 mm³) or experiencing recurrent or resistant infections (NCCN Guidelines Myelodysplastic Syndromes; AHFS);

OR

J. Individual is 18 years or older; **AND**

K. Individual is using for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation

OR

L. Individual is 2 years of age and older; **AND**

M. Individual is using for the acceleration of myeloid reconstitution following autologous or allogenic bone marrow transplantation or peripheral blood progenitor cell transplantation;

OR

N. Individual is 2 years of age and older; **AND**

O. Individual is using for the treatment of delayed neutrophil recovery or graft failure after autologous or allogenic bone marrow transplantation;

OR

P. Individual is using to increase survival in adult and pediatric individuals (from birth to 17 years of age) acutely exposed to myelosuppressive doses of radiation (such as Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS));

OR

Q. Individual is 18 years of age or younger; **AND**

R. Individual is diagnosed with relapsed/refractory high-risk neuroblastoma; **AND**

S. Individual is using in combination with dinutuximab (Unituxin), 13-cis-retinoic acid (i.e. isotretinoin) and interleukin-2 (IL-2) (i.e. aldesleukin); **AND**

T. Individual achieved a partial response to first-line multi-agent, multi-modality therapy (i.e. induction combination chemotherapy, or myeloablative consolidation chemotherapy followed by autologous stem cell transplant).

V. Requests for tbo-filgrastim (Granix) may be approved if the following criteria are met:

A. Individual with non-myeloid malignancy is using for primary prophylaxis of FN; **AND**

B. Individual has a risk of FN of 20% or greater based on chemotherapy regimen (see Appendix, Table 1);

OR

C. Individual with nonmyeloid malignancy is using for primary prophylaxis of FN; **AND**

D. Individual's risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy regimen and individual has any risk factors for FN:

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Applicable	X	X	X	X	X	X	X

1. Age greater than 65 years (Lyman 2014; Aagaard 2018); **OR**
2. Poor performance status (Eastern Cooperative Oncology Group 3 or 4) or HIV infection (in particular, those with low CD4 counts ($\leq 450/\mu\text{L}$)) but chemotherapy still indicated (Lyman 2014); **OR**
3. Prior radiation therapy (within previous 1 year) (Terbuch 2018) (Fujiwara 2017) (Shigeta 2015); **OR**
4. Bone marrow involvement by tumor producing cytopenias (Lyman 2014); **OR**
5. Persistent neutropenia (absolute neutrophil count [ANC] less than 1500mm^3) (Lyman 2014); **OR**
6. Poor renal function (glomerular filtration rate [GFR] less than $60\text{mL}/\text{min}$) (Lyman 2014; Aagaard 2018); **OR**
7. Liver dysfunction (liver function tests at least 2X upper limit of normal or bilirubin $> 2.0\text{ mg}/\text{dL}$) (Lyman 2014; Aagaard 2018); **OR**
8. Recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc.) (Lyman 2014; Aagaard 2018); **OR**
9. History of active infection within previous 60 days (Lyman 2014; Aagaard 2018); **OR**
10. Current open wound and chemotherapy cannot be delayed (Lyman 2014; Aagaard 2018);

OR

- E. Individual with nonmyeloid malignancy is using for secondary prophylaxis of FN; **AND**
- F. Individual has experienced a neutropenic complication from a prior cycle of chemotherapy (for which prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome (NCCN 2A);

OR

- G. Individual is using as an adjunctive treatment for FN;

AND

- H. Individual was previously using Granix (tbo-filgrastim) prophylactically (NCCN 2A);

OR

- I. Individual has not received prophylactic therapy with a granulocyte colony stimulating factor (NCCN Guidelines Myeloid Growth Factors);

AND

- J. Individual has a high risk for infection-associated complications as demonstrated by any of the following:
1. Expected prolonged (greater than 10 days) and profound (less than $0.1 \times 10^9/\text{L}$) neutropenia (NCCN 2A); **OR**
 2. Age greater than 65 years; **OR**
 3. Pneumonia or other clinically documented infections; **OR**
 4. Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
 5. Invasive fungal infection; **OR**

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Applicable	X	X	X	X	X	X	X

6. Prior episode of febrile neutropenia; **OR**
7. Hospitalized at the time of the development of fever;

OR

K. Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed (NCCN 2A);

OR

L. Individual has a diagnosis of myelodysplastic syndrome (MDS); **AND**
M. Individual has severe neutropenia (ANC less than or equal to 500mm³) or experiencing recurrent or resistant infections (NCCN 2A);

OR

N. Individual is using to mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT) (AHFS).

Colony Stimulating Factors (filgrastim, pegfilgrastim, sargramostim, and tbo-filgrastim) may **not** be approved for any of the following:

- I. Individual is using as prophylaxis for FN, except when criteria above are met; **OR**
- II. Individual is using as treatment in neutropenia in those who are afebrile, except when criteria above are met; **OR**
- III. Individual is using as adjunctive therapy in those with uncomplicated febrile neutropenia, defined as: fever less than 10 days duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies; **OR**
- IV. Individual is using for chemosensitization of myeloid leukemias; **OR**
- V. Individual is using for prophylaxis for FN during concomitant chemotherapy and radiation therapy; **OR**
- VI. Individual is continuing use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders); **OR**
- VII. Individual is using as a technique to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium.

Key References:

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Applicable	X	X	X	X	X	X	X

1. Aagaard T, Roen A, Reekie J., et.al. Development and Validation of a Risk Score for Febrile Neutropenia After Chemotherapy in Patients With Cancer: The FENCE Score. *JNCI Cancer Spectrum*. 2018; 2(4):1-8.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 28, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Fujiwara T, Kenmotsu H, Naito T, et.al. The incidence and risk factors of febrile neutropenia in chemotherapy-naïve lung cancer patients receiving etoposide plus platinum. *Cancer Chemother Pharmacol*. 2017; 79 (6):1229–1237
6. Gaut D, Tang K, Sim M, et.al. Granulocyte Colony-Stimulating Factor (G-CSF) Interactions with Chimeric Antigen Receptor (CAR) T-Cell Therapy for Diffuse Large B-Cell Lymphoma. *Blood*. 2019:Supp(1): 4109.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Updated periodically. Accessed on April 6, 2020
 - a. Acute Myeloid Leukemia. V3.2020. Revised December 23, 2019.
 - b. Hematopoietic Growth Factors. V2.2020. Revised January 27, 2020.
 - c. Myelodysplastic Syndromes. V2.2020. Revised February 28, 2020.
9. Lyman G, Abella E, and Pettengell R. Risk Factors for Febrile Neutropenia Among Patients With Cancer Receiving Chemotherapy: A Systematic Review. *Crit Rev Oncol Hematol*. 2014; 90 (3), 190-9.
10. Sasse EC, Sasse AD, Brandalise SR, et al. Colony stimulating factors for prevention of myelosuppressive therapy induced febrile neutropenia in children with acute lymphoblastic leukaemia. *Cochrane Database Syst Rev*. 2005; (3):CD004139.
11. Shigeta K, Kosaka T, Yazawa S. et. al. Predictive factors for severe and febrile neutropenia during docetaxel chemotherapy for castration-resistant prostate cancer. *Int J Clin Oncol*. 2015; 20(3):605–612.
12. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the Use of WBC Growth Factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-212.
13. Terbuch A, Posch F, Partl R, et al. Risk stratification for febrile neutropenia in patients with testicular germ cell tumors. *Cancer Medicine*. 2018; 7(2):508–514.

Appendix

Febrile Neutropenia Risk of Selected Chemotherapy Regimens

The following table represents selected chemotherapy regimens requiring further examination in their disease setting and the associated risk for development of febrile neutropenia. This is not a comprehensive list, as there are other regimens that are associated with risk for the development of FN. The FN risk of these other regimens will follow the guidance within the NCCN Guidelines Management of Neutropenia. A high-risk chemotherapy regimen is defined as a $\geq 20\%$ probability of developing febrile neutropenia, an intermediate-risk chemotherapy regimen is associated with $\geq 10\%$ to $\leq 20\%$ incidence of developing FN, and a low-risk chemotherapy regimen is associated with $<10\%$ incidence of developing FN.

Table 1

Disease State	Chemotherapy regimen	Risk of developing FN	References
Ovarian Cancer	Carboplatin and paclitaxel	Low	Clamp 2019; Coleman 2017; Katsumata 2009, 2013; Lhomme 2008; Pignata 2014; Sugiyama 2016; Vasey 2004
Ovarian Cancer (Advanced)	Topotecan	Intermediate	Aoki 2011; Gordon 2001, 2004; Gore 2002; McGonigle 2011; Meier 2009; Sehouli J 2008; Spannuth WA 2007; Swisher 1997
Non-Small Cell Lung Cancer (Metastatic)	Carboplatin/cisplatin, pemetrexed, and pembrolizumab	Low	Gandhi 2018; Langer 2016; Rodrigues-Pereira 2011; Scagliotti 2008

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Non-Small Cell Lung Cancer (Metastatic, non-squamous)	Carboplatin, paclitaxel, and atezolizumab ± bevacizumab	Low	Lilenbaum 2005; Ohe 2007; Socinski 2018; Williamson 2005
Non-Small Cell Lung Cancer (Metastatic, squamous)	Carboplatin, paclitaxel/nab-paclitaxel, and pembrolizumab	Low	Gadgeel 2018; Lilenbaum 2005; Ohe 2007; Paz-Ares 2018; Williamson 2005
Small Cell Lung Cancer (Extensive Stage)	Carboplatin, etoposide, and atezolizumab	Low	Horn 2018; Kosmidis 1994; Socinski 2009
Breast Cancer	Adjuvant TC	Intermediate	Do 2015; Jones 2009; Jones 2006; Kosaka 2015; Younis 2012
Pancreatic Cancer	FOLFIRINOX	Intermediate	Chlorean 2019; Conroy 2011; Conroy 2005; Hosein 2012; Okusaka 2014; Peddi 2012; Suker 2016; Thibodeau 2018; Tong 2018
Head and Neck Cancer (Recurrent/Metastatic)	EGFR-inhibitor (cetuximab or panitumumab) and platinum-based chemotherapy	Low	Burtness B 2005; Vermorken JB 2008; Vermorken JB 2013;
	Pembrolizumab plus platinum-based chemotherapy	Low	Burtness B 2019;
Soft Tissue Sarcoma (Advanced)	Doxorubicin	High	Judson I 2014; Lorigan P 2007; Nielsen OS 1998; Seddon B 2017; Tap WD 2017; Tap WD 2020
Castrate-Resistant Prostate Cancer (CRPC) (Advanced)	Cabazitaxel	Intermediate	De Bono JS. 2010; Eisenberger M 2017; Oudard S 2017
Breast Cancer (Advanced)	Docetaxel (dosing of 100 mg/m ² every 3 weeks or less)	Intermediate	Andersson M 2011; Baselga J 2012; Burris HA 1999; Harvey V 2006; Jones SE 2005; Marty M 2005;
Germ Cell Tumors (Advanced)	Bleomycin, etoposide, and cisplatin	Intermediate risk	de Wit R 2012; Fizazi K 2014; Garcia del Muro X 2008; Nichols CR 1991
	Etoposide and cisplatin	Intermediate risk	Arranz A 2001; Horwich A 2000; Motzer RJ 1995

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