CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Daratumumab (Darzalex) for Multiple Myeloma (second-line or beyond) (pCODR 10104)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: October 23, 2017

This information is current as of December 1, 2019.

Note: Funding criteria as listed on the decision date. Please refer to the provincial drug programs for the most recent funding criteria and program eligibility.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
BC	Funded	Feb 1, 2019	For treatment of patients with multiple myeloma who have received at least one prior line of therapy. • Patients must be sensitive to bortezomib or lenalidomide or not previously exposed • A BC Cancer "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment • Patients are eligible for only one triplet therapy, i.e either daratumumab or carfilzomib triplet therapy. • Patients on bortezomib or lenalidomide and dexamethasone and have not progressed on 1 February 2019, may add daratumumab if otherwise eligible.
AB	Funded	Jan 29, 2019	In combination with lenalidomide and dexamethasone or bortezomib and dexamethasone for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy. Not to be used as monotherapy in patients who are resistant to both bortezomib and lenalidomide and who were previously treated with three or more lines of therapy. Patients have access to one triple therapy – either daratumumab or carfilzomib triplet therapy Existing patients who have received three or more lines of therapy, none of which was a triplet combination, and who otherwise meet criteria for these regimens, should have access to a triplet therapy.

SK	Funded	Jul 15, 2019	In combination with Lenalidomide and Dexamethasone (DRd regimen) or Bortezomib and Dexamethasone (DVd regimen) for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy. Notes: •Daratumumab containing regimens are not funded when the disease is considered refractory to both Lenalidomide and Bortezomib •Patients are considered to be refractory to Lenalidomide and/or Bortezomib if they are receiving or previously received Lenalidomide (any dose) or Bortezomib, including maintenance therapy post-ASCT, and have experienced disease progression during or within 60 days of stopping therapy •Daratumumab will only be funded as a triplet in combination with either Lenalidomide-Dexamethasone (DRd) or Bortezomib-Dexamethasone (DVd); no other anti-myeloma treatment regimens will be funded in combination with Daratumumab •Either DRd or DVd can be chosen depending on drug sensitivities •Only one of the following triplet regimens will be funded per patient – either Daratumumab (DRd, DVd) or Carfilzomib-based (KRd) triplet therapy •Patients currently receiving either Lenalidomide-Dexamethasone (Rd) or Bortezomib-based therapy (e.g., CyBor-D) in the second-line setting will be eligible to have Daratumumab added to their second-line regimen provided there has been no disease progression, and all other funding eligibility criteria is met at the time of Daratumumab addition •Patients who continue to receive a Bortezomib-based regimen in the second-line setting without the addition of Daratumumab will be eligible to receive either DRd in the third-line setting provided the disease is not refractory to Lenalidomide, and all other funding eligibility criteria is met at the time of Daratumumab addition •Patients who continue to receive a Lenalidomide-based regimen in the second-line setting without the addition of Daratumumab will be eligible to receive DVd in the third-line setting provided the disease is not refractory to Bortezomib, and all other funding eligibility criteria is met at the time of Daratumumab addition •Daratumumab triplet therapy may be continued until disease progression or unacceptable toxicity Daratumumab is not funded in the following situations: •As a treatment switch in patients intolerant of first-line therapy without evidence of disease progression •As single agent salvage monotherapy •As part of re-induction prior to a second hematopoietic stem cell transplant (SCT), or as consolidation or maintenance following a SCT •Treatment of patients with monoclonal gammopathy of undetermined significance

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			(MGUS), smoldering myeloma, or amyloidosis without evidence of concomitant myeloma.
MB	Funded	Jan 8, 2019	In combination with lenalidomide and dexamethasone or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy.
ON	Funded	Mar 15, 2019	Daratumumab is used in combination with bortezomib and dexamethasone OR in combination with lenalinomide and dexamethasone for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy • CCO will fund one novel triplet therapy for relapsed multiple myeloma (either daratumumab-based or carfilzomib-based). • Patients whose disease is refractory to both lenalidomide and bortezomib are not eligible for publicly funded daratumumab. • Patients whose disease is refractory to any proteasome inhibitor (including bortezomib and carfilzomib) are not eligible for funding for the DVd regimen.
NS	Funded	May 1, 2019	In combination with bortezomib and dexamethasone, or lenalidamide and dexamethasone, for patients with multiple myeloma who have received at least one prior treatment. Patients must be sensitive to bortezomib, or lenalidamide, or not previously exposed. Treatment should be in patients who have a good performance status. Treatment with daratumumab should continue until disease progression or unacceptable toxicity.
NB	Funded	Apr 26, 2019	Daratumumab in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Patients must have a good performance status. Treatment with daratumumab should be discontinued upon disease progression or unacceptable toxicity. or Daratumumab in combination with lenalidomide and dexamethasone for the treatment of patients with multiple who have received at least one prior therapy. Patients must have a good performance status. Treatment with daratumumab should be discontinued upon disease progression or unacceptable toxicity.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NL	Funded	Aug 16, 2019	In combination with Lenalidomide and Dexamethasone, or Bortezomib and Dexamethasone for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy.
PEI	Under provincial consideration		

Under provincial consideration means that the province is reviewing pCODR's recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level. This may occur before or after the pan-Canadian Pharmaceutical Alliance negotiations. Please contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.