Regimen Monograph

A - Regimen Name

DARADEXALENA Regimen

daratumumab-dexamethasone-lenalidomide

Disease Site

Hematologic
Multiple Myeloma

Intent

Palliative

Regimen Category

Evidence-Informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses

For the treatment of:

- newly diagnosed multiple myeloma, in patients who are not eligible for autologous stem cell transplant and have good performance status
- patients with relapsed or refractory multiple myeloma who have received one or more prior lines of therapy

Supplementary Public Funding

daratumumab
New Drug Funding Program (Daratumumab - In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma)

daratumumab
New Drug Funding Program (Daratumumab in Combination with Lenalidomide

and Dexamethasone for Newly Diagnosed Transplant Ineligible Multiple Myeloma) (NDFP Website)

dexamethasone
ODB - General Benefit (dexamethasone) (ODB Formulary)

lenalidomide
ODB Limited Use (lenalidomide - For the treatment of patients with multiple myeloma, who are deemed to be lenalidomide sensitive, and/or have not experienced progression while on a lenalidomide-based regimen in the treatment or maintenance setting, according to clinical criteria) (ODB Formulary)

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B - Drug Regimen

Note: Different daratumumab products are NOT INTERCHANGEABLE.

Cycles 1 to 2:

daratumumab[1]	16 mg /kg	IV	Days 1*, 8, 15, 22
dexamethasone†	40** mg	PO	Days 1, 8, 15, 22
lenalidomide[2]	25 mg	PO	Days 1 to 21

Q28 Days

Cycles 3 to 6:

daratumumab[1]	16 mg /kg	IV	Days 1 and 15
dexamethasone†	40** mg	PO	Days 1, 8, 15, 22
lenalidomide[2]	25 mg	PO	Days 1 to 21

Q28 Days

Cycle 7 and beyond:

daratumumab[1]	16 mg /kg	IV	Day 1
dexamethasone†	40** mg	PO	Days 1, 8, 15, 22
lenalidomide[2]	25 mg	PO	Days 1 to 21

Q28 Days

1. Daratumumab infusion should be administered at the appropriate initial infusion rate with incremental escalation. Subsequent infusion rate escalation or dilution reduction should only be considered if the previous infusion was well-tolerated. See the Administration section for details.

2. Lenalidomide may only be prescribed and dispensed by physicians and pharmacists registered with a controlled distribution program. Patients must also be registered and meet all conditions of the program.

*Splitting the first dose over 2 days has been described (8 mg/kg days 1 and 2) and may be considered. The same premedications should be administered prior to both treatment days (Reece et al 2018). See Premedication and Supportive Measures section for details.

**Dexamethasone may be given as 20mg pre-medication, on the days of daratumumab infusion, and 20mg post-medication, the days after the infusion.

†The dexamethasone dose should be reduced in elderly patients.

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

- HBV screening should be performed in all patients prior to starting treatment.
- Daratumumab can interfere with cross-matching for blood transfusions; type and screen and RBC genotyping tests should be done before starting this drug.
- For lenalidomide, patients must be registered and meet all conditions of lenalidomide's controlled distribution program, including contraception.
- Women of child bearing potential must have two negative pregnancy tests before initiating treatment. Assess risk of second primary malignancies prior to starting treatment.
- Optimal control of thyroid function is recommended prior to starting lenalidomide treatment.
- Consider antiviral prophylaxis for herpes zoster reactivation.
- Consider prophylaxis for venous thromboembolism. For patients who are not at high risk for bleeding or VTE, either low-dose aspirin 81-100 mg PO daily or enoxaparin 40mg SC daily can be used.
- Careful consideration and monitoring must be taken with erythropoietin stimulating agents (ESAs), since the concomitant use of ESAs with lenalidomide may potentiate the risk of thrombosis.
- RBC or platelet transfusions with lenalidomide dose reductions/interruptions may be appropriate in severe / symptomatic anemia or thrombocytopenia.

Pre-medications (prophylaxis for infusion reaction):

To be given at least 1 hour prior to daratumumab infusion:

- Dexamethasone 20 mg IV/PO*
- Oral antipyretic (e.g. acetaminophen 650-1000 mg)
- H1-receptor antagonist IV/PO (e.g. diphenhydramine 25-50 mg or equivalent)
- Famotidine 20 mg IV (or equivalent)
- Montelukast 10 mg PO**

*Administer IV prior to the first infusion; Oral administration may be considered prior to subsequent infusions. Dexamethasone on the day of infusion may be given as part of pre-/post-medications for daratumumab; 20 mg IV/PO

on the day of daratumumab infusion and 20 mg PO on the day after infusion. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab infusion in some clinical trials.

**The addition of montelukast given prior to the first infusion numerically reduced the incidence of respiratory infusion reactions in the study by Nooka et al.

Post-infusion medications (prevention of delayed reactions):

- Dexamethasone 20 mg PO on the day after daratumumab infusion*
- Consider bronchodilators (e.g. short and long acting) and inhaled corticosteroids (for patients with a history of COPD)&****

*Dexamethasone on the day of infusion may be given as part of pre-/post-medications for daratumumab; 20 mg IV/PO on the day of daratumumab infusion and 20 mg PO on the day after infusion. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab infusion in some clinical trials.

&Consider adding an H1-receptor antagonist if the patient is at higher risk of respiratory complications.

***These may be discontinued after the 4th infusion if no major IRs occurred.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Women of child bearing potential must have two negative pregnancy tests before initiating lenalidomide treatment.

Assess risk of second primary malignancies prior to starting lenalidomide treatment.

Dosage with toxicity

Daratumumab dose reductions are not recommended. Doses were held for toxicity as suggested below and missed doses were not made up. Discontinue daratumumab if a dose is delayed by more than 28 days.

For lenalidomide, dose reductions were permitted at the following dose levels:

Dose level	Lenalidomide dose (mg)
0	25

-1	15
-2	10
-3	5
-4	Discontinue

Suggested dose modifications:

Toxicity	Daratumumab	Lenalidomide (counts x 10^9/L)
Thrombocytopenia	Hold* for grade 3 or higher thrombocytopenia with bleeding	Hold when platelet count first falls to < 30, monitor CBC weekly When count returns to ≥ 30, resume at one dose level reduction. For recurrence: Hold; when count returns to ≥ 30, resume at one dose level reduction.
Neutropenia	Hold* for grade 4 hematologic toxicity	Hold when ANC first falls to < 1, start G-CSF support, monitor CBC weekly. When count returns to ≥ 1 and neutropenia is only observed toxicity, resume at the previous dose. When count returns to ≥ 1 and other toxicity is observed, resume at one dose level reduction. For recurrence: Hold; when count returns to ≥ 1, resume at one dose level reduction.
Grade 2 or 3 rash	n/a	Hold or consider discontinuing
Grade 4 skin rash, OR Exfoliative or bullous rash, OR Suspected Stevens	Discontinue	

Johnson Syndrome, Toxic epidermal necrolysis or DRESS		
Increased LFTs	n/a	Hold and consider restarting at a lower dose when ≤ baseline.
Other Grade 3 or 4 non-hematologic toxicities**	Hold*	If related to lenalidomide, hold until ≤ grade 2. Resume at one dose level reduction.
Pneumonitis OR Progressive multifocal leukoencephalopathy	Discontinue	
Angioedema or anaphylaxis	Discontinue	
Solid organ transplant rejection	Discontinue	
HBV reactivation	Hold treatment (including steroids). Consult with a HBV expert and manage appropriately. Restart of treatment in patients whose HBV reactivation is adequately controlled should be discussed with physicians with expertise in managing HBV.	

*Resume when toxicity has resolved to ≤ grade 2

**except for grade 3 nausea/vomiting responsive to antiemetics, grade 3 diarrhea responsive to antidiarrheals, isolated grade 3 GGT elevation or grade 3 fatigue for < 7 days post-infusion

Management of Daratumumab Infusion-related Reactions:

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

Grade	Management	Re-challenge
1 or 2	• Stop or slow the infusion rate. • Manage the symptoms.	• Re-challenge with pre-medications and with infusion rate modification (eg. Table D

	Restart: • Once symptoms have resolved, the infusion may be restarted at a rate of no more than 50% of the rate at which the reaction occurred. • If no reaction occurs, escalate the rate at no more than 50 mL/hour every hour.	in Drug Administration and Special Precautions section).
3	• Stop treatment. • Aggressively manage symptoms. **Restart:** • Once symptoms have resolved, the infusion may be restarted at a rate of no more than 50% of the rate at which the reaction occurred. • If no reaction occurs, escalate the rate at no more than 50 mL/hour every hour.	• Re-challenge with pre-medications and with infusion rate modification (eg. Table D in Drug Administration and Special Precautions section). • If a grade 3 IR recurs for the 3rd time, discontinue permanently (do not re-challenge).
4	• Stop treatment. • Aggressively manage symptoms.	• Discontinue permanently (do not re-challenge).

Hepatic Impairment

For dexamethasone, no dosage adjustment is required.

Hepatic Impairment	Lenalidomide dose	Daratumumab Dose
Mild (total bilirubin 1 to 1.5 times ULN or AST > ULN)	No dose adjustment necessary	
Moderate (total bilirubin >1.5 to 3 times ULN and any AST)	No data	

Severe impairment (total bilirubin >3 times ULN and any AST)	

Renal Impairment

For dexamethasone, no dosage adjustment is necessary.

Daratumumab is not renally cleared. For lenalidomide, clearance is decreased in renal impairment. The following dosage adjustments are suggested:

CrCl (mL/min)	Lenalidomide starting dose*	Daratumumab Dose
30-60	10 mg daily	No dose adjustment necessary
< 30 not requiring dialysis	15 mg every other day	
< 30 requiring dialysis	5 mg daily (after dialysis on dialysis days)	

*maintain day 1-21, q28 day schedule

Dosage in the Elderly

For daratumumab, no overall differences in efficacy was observed, but patients ≥ 65 years were more likely to experience serious adverse events (e.g., pneumonia) than those < 65 years.

For lenalidomide, the incidences of adverse events were significantly higher in patients over 65, including constipation, confusion, dyspnea, atrial fibrillation, diarrhea, fatigue, pulmonary embolism and syncope. This may be related to renal impairment. Monitor elderly patients closely and adjust the dose for renal impairment as suggested under "dosage with renal impairment".

Patients older than 75 or those with a BMI < 18.5 received dexamethasone at a reduced dose of 20 mg weekly in some clinical trials.

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F - Adverse Effects

Refer to daratumumab, dexamethasone, lenalidomide, drug monograph(s) for additional details of adverse effects.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Myelosuppression +/- bleeding, infection (may be severe, including opportunistic infection, viral reactivation) • Diarrhea	• Infusion related reaction (daratumumab; includes CRS / anaphylaxis, may be severe) • Edema • Constipation • Fatigue • Musculoskeletal pain • Nausea, vomiting • Cough, dyspnea	• Peripheral neuropathy • Anorexia, weight loss • Abnormal electrolytes • Dizziness • Headache • Rash (may be severe) • Tremor • Blurred vision • Hypertension (may be severe) • Abdominal pain • Dysgeusia • Corticosteroid effects (GI irritation, mood changes, hyperglycemia, insomnia)	• Arterial / venous thromboembolism • Arrhythmia • Cardiotoxicity • Hypotension • ↓Immunoglobulins • Nephrotoxicity • Hepatotoxicity • Pancreatitis • Cholecystitis • Secondary malignancy • Adrenal insufficiency • Hyper/hypothyroidism • Hypersensitivity • SJS, TEN • DRESS • Rhabdomyolysis • Hemolysis • PML • Tumour lysis syndrome • Pneumonitis • Corticosteroid effects (osteoporosis, cataracts) • Solid organ transplant rejection • GVHD

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G - Interactions

Refer to daratumumab, dexamethasone, lenalidomide, drug monograph(s) for additional details

- Lenalidomide increases the concentration of digoxin. Use caution and monitor digoxin levels.

- Lenalidomide increases the risk of thromboembolism, and can have an additive effect with hormonal therapy, erythropoietic agents, and corticosteroids.
- Daratumumab interferes with indirect antiglobulin (Coombs) test by binding to CD38 on RBCs. Daratumumab-mediated positive Coombs test may persist for up to 6 months after treatment completion. Blood should be typed and screened prior to initiating treatment. Notify blood transfusion centres of this in the event of a planned transfusion and educate patients.
- Daratumumab may interfere with the serum protein electrophoreses (SPE) and immunofixation (IFE) assays used to monitor M-protein. This can impact the monitoring of response and disease progression in some patients with IgG kappa myeloma protein.

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H - Drug Administration and Special Precautions

Refer to daratumumab, dexamethasone, lenalidomide, drug monograph(s) for additional details.

Administration

Daratumumab

Daratumumab IV and subcutaneous formulations are **not interchangeable**. The dosing and administration of these products are different.

Daratumumab infusion should be administered at the appropriate initial infusion rate with incremental escalation. Subsequent infusion rate escalation or dilution reduction should only be considered if the previous infusion was well-tolerated (Table D).

Table D: Standard infusion rates

	Dilution volume	Initial Infusion Rate (1st hr)	Increments of infusion rate	Max infusion rate	Approximate infusion time
Week 1 (single dose infusion)	1000 mL	50 mL/hr	50 mL/hr every hour	200 mL/hr	6.5 hr
Week 1 (split dose infusion; applicable to days 1 and 2)	500 mL	50 mL/hr	50 mL/hr every hour	200 mL/hr	4 hr
Week 2[a]	500 mL	50 mL/hr	50 mL/hr every hour	200 mL/hr	4 hr

Subsequent Infusions[b,c]	500 mL	100 mL/hr	50 mL/hr every hour	200 mL/hr	3.25 hr

[a] If single dose infusion is used for week 1, the 500 mL dilution volume for the 16 mg/kg dose should be used only if there were no IRRs in the previous week.

[b] Initial infusion rate should only be modified if treatment in Weeks 1 and 2 were well-tolerated (no ≥ grade 1 IRRs during ≥100 mL/hr).

[c] If the patient did not experience an IR in the first 2 infusions of daratumumab, consideration can be given to administer daratumumab as a rapid infusion starting with the 3rd dose (20% of the dose over 30 minutes at 200 mL/hour, then the remaining 80% of the dose over 60 minutes at 450 mL/hour).

- Missed doses should be administered as soon as possible and the dosing schedule adjusted accordingly. The treatment interval should be maintained.
- Daratumumab should be diluted in 0.9% Sodium Chloride; remove a volume from the IV bag that is equal to the required volume of daratumumab solution.
- Daratumumab solution is colourless to yellow.
- The diluted solution may develop very small, translucent to white proteinaceous particles. Do not use if opaque particles, discolouration, or other foreign particles.
- Administer by IV infusion using an infusion set with a flow regulator and an in-line, low protein-binding filter (0.22 or 0.2 µm).
- The infusion bag must be made of PVC, polypropylene (PP), polyethylene (PE) or polyolefin blend (PP+PE).
- Polyurethane (PU), polybutadiene (PBD), PVC, PP, or PE administration sets must be used.
- Do not infuse concomitantly in the same IV line with other agents.
- Store vials at 2^{o}C - 8^{o}C
- Do not shake or freeze, protect from light.

Also refer to the CCO guideline for detailed description of Management of Cancer Medication-Related Infusion Reactions.

Lenalidomide

- Drug available by outpatient prescription in pharmacy registered with a controlled distribution program.
- Swallow capsules whole; they should not be broken, chewed, or opened. Do not extensively

handle the capsules.

- Administer capsules preferably with water, either with or without food. Do not remove from blister packs until ready to take the dose.
- Note: Females who could become pregnant, or who plan to become pregnant can handle lenalidomide capsules if they are using latex gloves.
- If a dose is missed, it may be taken up to 12 hours after the time it is normally taken. Otherwise, skip this and take the next dose on the following day at its usual scheduled time.
- Store capsules at room temperature (15 to 30°C).

Dexamethasone

- Oral tablets for self-administration
- Given with food, preferably in the morning
- Store tablets at room temperature

Contraindications

- Patients with a history of severe hypersensitivity to daratumumab or who have hypersensitivity to lenalidomide, pomalidomide, thalidomide or dexamethasone or who have hypersensitivity to any ingredients in the formulations or components of the containers.
- Pregnant or breastfeeding women.
- Women at risk of being pregnant and male patients who do not comply with contraception requirements.

Other Warnings/Precautions

- Daratumumab can cause severe infusion-related reactions (IRRs), including anaphylaxis. It should only be administered by healthcare professionals with appropriate medical support to manage these reactions. Pre and post infusion medications should be administered (see Premedication and Supportive Measures section).
- Lenalidomide contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption
- Use with caution and consider venous thromboembolism prophylaxis when used in combination with corticosteroids or thrombogenic agents, such as hormones and erythropoietin (see adverse effects section)

- Exercise caution in patients with a history of venous thromboembolism or risk factors for arterial thromboembolism (e.g. hypertension and hyperlipidemia), or risk factors for atrial fibrillation (e.g. electrolyte abnormalities, pre-existing heart disease, hypertension, infection).
- Use with caution in patients with high tumour burden; monitor closely and use appropriate precautions for tumour lysis syndrome.
- Use with caution and monitor closely in patients with previous viral infections such as HBV and herpes zoster.
- Lenalidomide may be associated with fatigue and dizziness; caution is required when driving or operating machinery.

Pregnancy and Lactation

- This regimen is contraindicated in pregnancy and in females and males of childbearing potential who do not comply with the contraception conditions of lenalidomide's controlled distribution program. Refer to the controlled distribution program for full details.
- Breastfeeding is contraindicated.
- Fertility Effects:
  - Daratumumab: Unknown
  - Lenalidomide: Unlikely

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- CBC; Baseline and before each dose of daratumumab; if daratumumab is held, before each cycle of lenalidomide and as clinically indicated
- Blood; type and screen prior to starting daratumumab. In the event of a planned transfusion, notify blood transfusion centres.
- Liver function tests; Baseline, at each visit and as clinically indicated
- Renal function tests and electrolytes; Baseline, at each visit, and as clinically

indicated

- Thyroid function tests; Baseline and as clinically indicated
- Pregnancy testing requirements for women of child-bearing potential; Before starting and as indicated
- Immunoglobulin levels; Baseline and as clinically indicated
- HBV serology; Baseline for all patients and as clinically indicated. For patients with evidence of HBV serology at baseline, monitor during treatment and for at least 6 months post treatment. Consult with an expert in HBV
- Cancer screening for occurrence of second primary malignancy; Assess risk prior to starting treatment; then at each visit or as clinically indicated
- Clinical toxicity assessments and grading of infusion-related reactions with daratumumab, hypersensitivity, cardiac, neurologic and respiratory symptoms, rash, diarrhea, fatigue, constipation, infection (including viral reactivation), anemia, bleeding, tumour lysis syndrome, thromboembolism; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- ECG; Baseline; repeat if arrhythmia suspected
- INR in patients receiving warfarin; Baseline and as clinically indicated

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J - Administrative Information

Dexamethasone and lenalidomide: outpatient prescriptions for home administration

Daratumumab infusion:

Approximate Patient Visit	2.5 to 7.5 hours (depending on duration of daratumumab infusion)
Pharmacy Workload (average time per visit)	37.85 minutes
Nursing Workload (average time per visit)	74.83 minutes

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K - References

Daratumumab and lenalidomide drug monographs, Cancer Care Ontario.

Dimopoulos MA, Oriol A, Nahi H, et al; POLLUX Investigators. Daratumumab, Lenalidomide, and Dexamethasone for Multiple Myeloma. N Engl J Med. 2016 Oct 6;375(14):1319-1331.

Facon T, Kumar S, Plesner T, et al. Daratumumab plus Lenalidomide and Dexamethasone for Untreated Myeloma. N Engl J Med. 2019 May 30;380(22):2104-15.

Nooka AK, Gleason C, Sargeant MO, et al. Managing Infusion Reactions to New Monoclonal Antibodies in Multiple Myeloma: Daratumumab and Elotuzumab. J Oncol Pract. 2018 Jul;14(7):414-22.

pCODR expert review committee final recommendation: daratumumab (with lenalidomide and dexamethsone in newly diagnosed multiple myeloma). March 5, 2020.

PEBC Advice Documents or Guidelines

- Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline

September 2022 Changed Lenalidomide to ODB LU

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public

funding information.

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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