Empliciti® (elotuzumab) FOR INJECTION FOR INTRAVENOUS USE 300 MG & 400 MG VIALS

Bristol Myers Squibb®
Access Support®

A REFERENCE GUIDE TO

Reimbursement and Coding for EMPLICITI® (elotuzumab)

for injection, for intravenous use
(300 mg and 400 mg vials)

POMALYST® (pomalidomide) and REVLIMID® (lenalidomide) are only available through restricted distribution programs called POMALYST REMS® and Lenalidomide REMS.

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

Indications

EMPLICITI® (elotuzumab) is indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies.

EMPLICITI® (elotuzumab) is indicated in combination with POMALYST and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

REVLIMID® (lenalidomide) is a thalidomide analogue indicated for the treatment of adult patients with multiple myeloma (MM) in combination with dexamethasone (dex).

REVLIMID is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).

REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

POMALYST® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

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For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Select Important Safety Information

REVLIMID & POMALYST Boxed WARNINGS

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS AND ARTERIAL THROMBOEMBOLISM

EMBRYO-FETAL TOXICITY: REVLIMID & POMALYST are thalidomide analogues and are contraindicated in pregnancy. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting treatment and use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment. To avoid embryo-fetal exposure, REVLIMID and POMALYST are only available through their respective restricted distribution programs, Lenalidomide REMS and POMALYST REMS®.

Information about the Lenalidomide REMS program is available at www.lenalidomiderems.com or by calling 1-888-423-5436 and POMALYST REMS program is available at www.pomalystrems.com or by calling 1-888-423-5436.

HEMATOLOGIC TOXICITY: REVLIMID can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS had to have a dose delay/reduction during the major study. Thirty-four percent of patients had to have a second dose delay/reduction. Grade 3 or 4 hematologic toxicity was seen in 80% of patients enrolled in the study. Patients on therapy for del 5q MDS should have their complete blood counts monitored weekly for the first 8 weeks of therapy and at least monthly thereafter. Patients may require dose interruption and/or reduction. Patients may require use of blood product support and/or growth factors.

VENOUS AND ARTERIAL THROMBOEMBOLISM: REVLIMID & POMALYST have demonstrated a significantly increased risk of deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke in patients with MM. Thromboprophylaxis is recommended and the choice of regimen should be based on assessment of the patient's underlying risk factors. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling.

EMPLICITI with lenalidomide and dexamethasone (ERd) or pomalidomide and dexamethasone (EPd) is associated with Warnings and Precautions related to: Infusion Reactions, Infections, Second Primary Malignancies, Hepatotoxicity, Interference with Determination of Complete Response, Pregnancy/Females and Males of Reproductive Potential, and Adverse Reactions.

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Bristol Myers Squibb Is Committed to Helping Support Access

This brochure is designed to help appropriate patients get access to our medications by providing helpful reimbursement information for healthcare offices. Healthcare benefits vary significantly; therefore, it is important that oncology offices verify each patient's insurance coverage prior to initiating therapy.

Table of Contents

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

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Multiple Myeloma: ICD-10-CM Codes for EMPLICITI® (elotuzumab)

ICD-10-CM codes are used to identify a patient's diagnosis. On October 1, 2015, the newest version of these codes, ICD-10-CM, was implemented throughout the United States. This version replaces the previous version, ICD-9-CM.

The ICD-10-CM diagnosis codes contain **categories, subcategories,** and **codes**. Characters for categories, subcategories, and codes may be letters or numerals.

- **All categories** are 3 characters
- **Subcategories** are either 4 or 5 characters
- **Codes** may be 3, 4, 5, 6, or 7 characters
- The ICD-10-CM codes for the labeled indication for EMPLICITI are provided below by Bristol Myers Squibb and should be verified with the payer. Some health plans and Medicare insurers may specify which codes are covered under their policies. Please code to the level of specificity documented in the medical record. For additional coding questions, call BMS Access Support® at **1-800-861-0048** or visit **www.BMSAccessSupport.com**

ICD-10-CM Codes for EMPLICITI[1]	
C90 Multiple myeloma and malignant plasma cell neoplasms	
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

Note: If infusion is the only reason for the patient encounter, physicians and hospitals may report the code below as the primary diagnosis[1]:

Z51.12 Encounter for antineoplastic immunotherapy

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Healthcare Common Procedure Coding System (HCPCS) and Revenue Codes for EMPLICITI® (elotuzumab)

HCPCS Code for EMPLICITI[2]		
HCPCS Code	Description	Billing Units
J9176	Injection, elotuzumab, 1 mg	1 mg = 1 billing unit

Please contact the payer for additional coding information regarding EMPLICITI.

Depending on payer preferences for billing and coding, the billing unit conversion for claim submission may vary. Therefore, the provider should confirm preference with the payer prior to submitting.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

Use the following claim formats when EMPLICITI is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)
- Hospital outpatient: UB-04 (CMS-1450) (paper format) or ASC 837I (electronic format)
- **JW modifier** – Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals.[3] Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records

All the coding information presented is applicable to outpatient procedures only. Please see pages 9-10 for more information.

Revenue Codes[4] (for Use in the Hospital Outpatient Setting)	
Revenue Code	Description
0636	Drugs requiring detailed coding
0335	Chemotherapy administration, IV
0260	IV therapy

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Current Procedural Terminology (CPT) Codes for the Administration of EMPLICITI® (elotuzumab)

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.

CPT* codes that may be appropriate when administering EMPLICITI appear in the table below.

CPT Codes for EMPLICITI[5]

CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Each additional hour • List separately in addition to code for primary procedure • Use 96415 in conjunction with 96413 • Report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments

Please contact the payer or BMS Access Support® for additional coding information regarding EMPLICITI.

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National Drug Code (NDC) Information for EMPLICITI® (elotuzumab)

The NDCs for EMPLICITI, listed in the table below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

NDC Information for EMPLICITI[6]

300 mg single-dose vial		400 mg single-dose vial
0003-2291-11		0003-4522-11
00003-2291-11		00003-4522-11

The red zero (red text) converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

Storage[6]

Store EMPLICITI under refrigeration at 2 °C to 8 °C (36 °F to 46 °F). Protect EMPLICITI from light by storing in the original package until time of use. Do not freeze or shake.

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5010 Electronic Transaction Coding for EMPLICITI® (elotuzumab)

- For electronic transactions, including 837P and 837I, the NDC is to be preceded by the qualifier N4 and followed immediately by the 11-digit NDC code for payers that require it[7]
- This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or mL (milliliter), and the quantity administered[7]

5010 Transaction Coding for EMPLICITI[6,7]

How Supplied	NDC	NDC Qualifier	NDC Basis of Measurement	Sample NDC 5010 Format
300 mg (lyophilized powder) single-dose vial	00003-2291-11	N4	UN	N400003229111UN1
400 mg (lyophilized powder) single-dose vial	00003-4522-11	N4	UN	N400003452211UN1

The examples given in the far-right column demonstrate NDC quantity reporting for 1 vial of EMPLICITI. The actual amount of drug used can vary based on factors such as patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.

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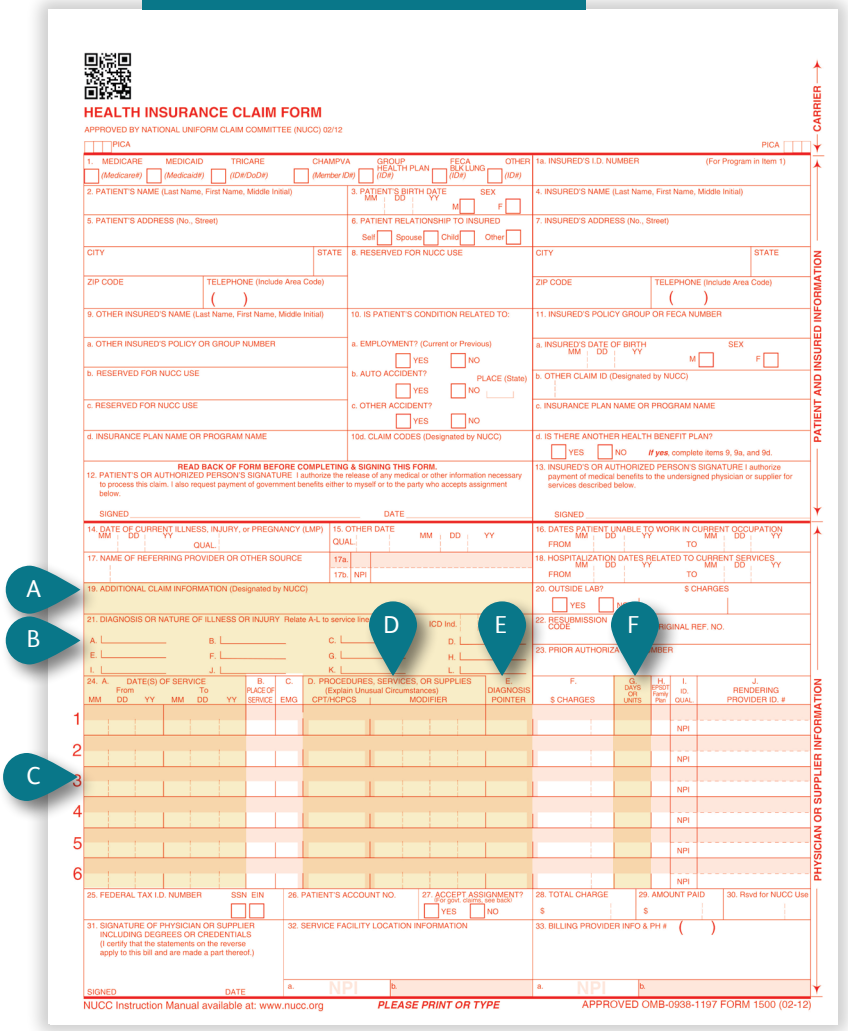
Coding and Billing Units for EMPLICITI® (elotuzumab)

Please contact the payer or BMS Access Support® for additional information on coding and billing units.

CMS-1500 Form


HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI

2 NPI

3 NPI

4 NPI

5 NPI

6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

A B C D E F

This sample form is for informational purposes only.

Physician Office

A **Item 19:** Many payers require detailed information about the drug in Box 19. Typically, payers require the drug name, total dosage and strength, and a concise description of an "unlisted procedure code" or a "Not Otherwise Classified" NOC code[7]

B **Item 21:** Enter the appropriate ICD-10-CM diagnosis codes for the type of multiple myeloma being treated[7]

C **Item 24A:** NDC information is required in the shaded area above the line on which a drug is reported in 24D.[7] The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (UN) and the quantity administered. For example, use "N400003229111UN1" for the 300-milligram (mg) vial or "N400003452211UN1" for the 400-mg vial[6,7]

D **Item 24D:** Enter the relevant HCPCS (J9176) and CPT codes (96413 for EMPLICITI infusion, and 96415 for each additional hour for infusions longer than 90 minutes).[2,5,7] In addition, it is required that you enter J9176-JW on the next line to record waste[3]

E **Item 24E:** Enter the diagnosis code reference letter or number from Box 21 that relates to the date of service and the services or procedures performed that are entered on that same line under 24D[7]

F **Item 24G:** Billing units are reported here.[7] 1 mg = 1 billing unit

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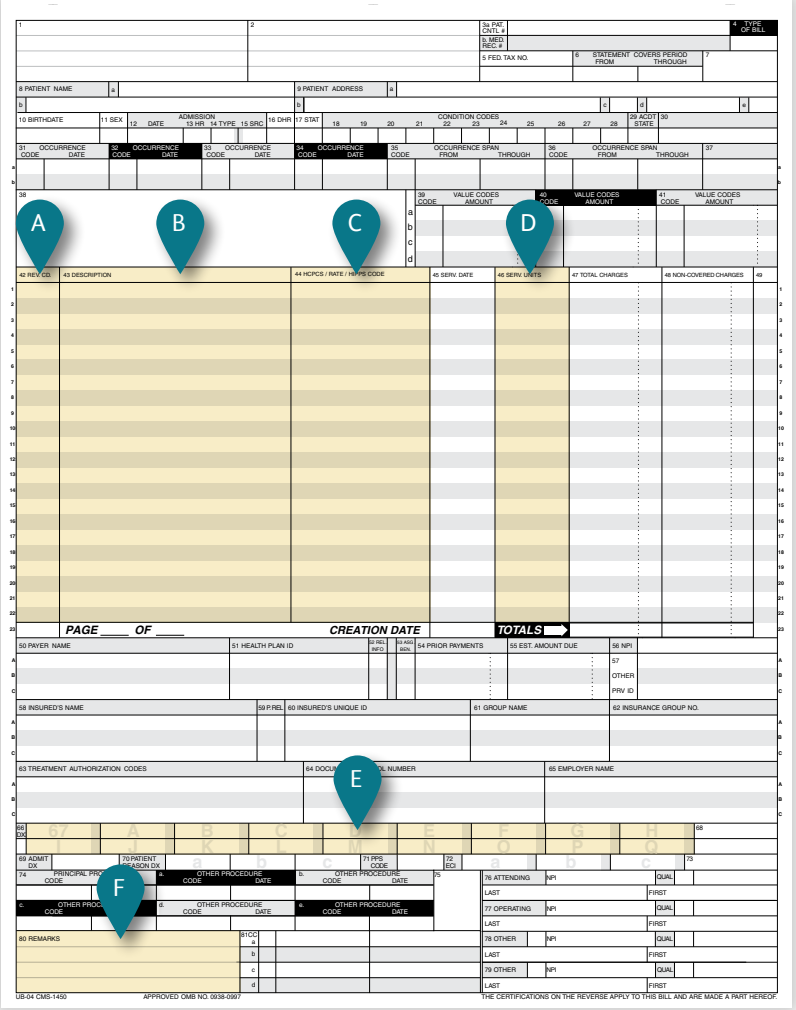
Coding and Billing Units for EMPLICITI® (elotuzumab) (cont'd)

UB-04 Form



This sample form is for informational purposes only.

Outpatient Hospital

A **Form Locator (FL) 42:** Enter the 4-digit revenue code that best describes the service provided, in accordance with hospital billing policy.[8] For chemotherapy administration, revenue codes 0260 (intravenous [IV] therapy) or 0335 (radiology–therapeutic: chemotherapy–IV) could be used.[4] The Centers for Medicare & Medicaid Services (CMS) recommends using revenue code 0636 (drugs requiring detailed coding)[9]

B **FL 43:** Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[8] Report the quantity qualifier (UN) followed by the quantity administered (300 mg or 400 mg). For example, use "N400003229111UN1" for the 300-mg vial or "N400003452211UN1" for the 400-mg vial[6,8]

C **FL 44:** Enter the relevant HCPCS (J9176) and CPT codes (96413 for EMPLICITI infusion, and 96415 for each additional hour for infusions longer than 90 minutes).[2,5,8] In addition, it is required that you enter J9176-JW on the next line to record waste[3]

D **FL 46:** Billing units are called service units and are placed here.[8] 1 mg = 1 billing unit

E **FLs 67A-67Q:** Enter the appropriate ICD-10-CM diagnosis codes for the type of multiple myeloma being treated[8]

F **FL 80:** Some payers require detailed information about the drug in FL 80.[8] Typically, payers require the drug name, total dosage and strength, method of administration, 11-digit NDC, and basis of measurement

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Dosing and Administration for EMPLICITI® (elotuzumab)

EMPLICITI dosing in combination with lenalidomide and dexamethasone[6]

- Patients must be premedicated before each dose of EMPLICITI as described below
- When administered with lenalidomide and dexamethasone, the recommended dosage of EMPLICITI is 10 mg/kg administered intravenously (IV):
  - Once a week for the first 2 cycles (28-day cycles)
  - Once every 2 weeks for cycle 3 onward (28-day cycles)
  - Continue treatment until disease progression or unacceptable toxicity

Pretreatment on days that EMPLICITI is administered[6]	
3-24 hours prior	**45-90 minutes prior**
Oral dexamethasone: 28 mg	8 mg IV dexamethasone + H_1 blocker: diphenhydramine (25-50 mg orally or IV) or equivalent + H_2 blocker + Acetaminophen (650-1000 mg orally)

Please see the EMPLICITI, lenalidomide, and dexamethasone dosing schedule on the next page.

Please refer to the EMPLICITI, lenalidomide, and dexamethasone Full Prescribing Information for additional information.

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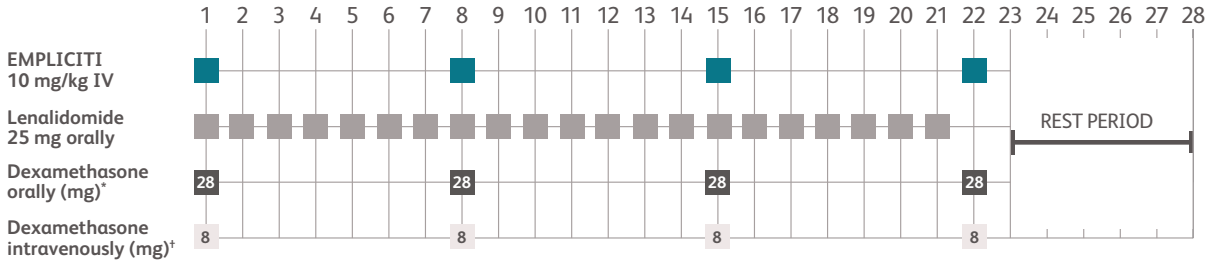
Dosing and Administration for EMPLICITI® (elotuzumab) (cont'd)

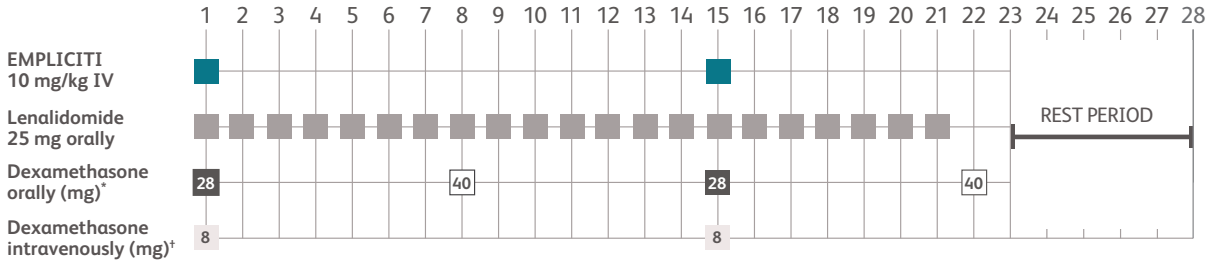
EMPLICITI dosing in combination with lenalidomide and dexamethasone[6]

EMPLICITI + lenalidomide and dexamethasone dosing schedule

Cycles 1 and 2 (28 days each): EMPLICITI dosed once a week



Cycles 3 and onward (28 days each): EMPLICITI dosed once every 2 weeks



On days that EMPLICITI is not administered, but a dose of dexamethasone is scheduled, (Days 8 and 22 of cycle 3 and all subsequent cycles) dexamethasone 40 mg should be given orally.[6]

*Oral dexamethasone (28 mg) taken between 3 and 24 hours before EMPLICITI infusion.

†Dexamethasone intravenously and other premedications are given 45-90 minutes prior to EMPLICITI infusion.

Please refer to the EMPLICITI, lenalidomide, and dexamethasone Full Prescribing Information for additional information.

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Dosing and Administration for EMPLICITI® (elotuzumab) (cont'd)

Important Dosing Information for REVLIMID® (lenalidomide)[10]

- The capsules should not be opened, broken, or chewed
- REVLIMID is primarily excreted unchanged by the kidney. Since elderly patients are more likely to have decreased renal function, care should be taken in dose selection. Monitor renal function
- Monitor complete blood counts (CBCs) every 7 days (weekly) for the first 2 cycles, on Days 1 and 15 of Cycle 3, and every 28 days (4 weeks) thereafter
- Treatment is continued or modified based on clinical and laboratory findings
- Dose modification guidelines are recommended to manage Grade 3/4 neutropenia or thrombocytopenia. For other Grade 3/4 toxicities judged to be related to lenalidomide, hold treatment and restart at next lower dose level when toxicity has resolved to ≤Grade 2
- Patients may require dose interruption and/or reduction
- Patients may require the use of blood product support and/or growth factors

Please refer to the EMPLICITI, lenalidomide, and dexamethasone Full Prescribing Information for additional information.

(continued on next page)

Dosing and Administration for EMPLICITI® (elotuzumab) (cont'd)

EMPLICITI dosing in combination with pomalidomide and dexamethasone[6]

- Patients must be premedicated before each dose of EMPLICITI as described below
- When administered with pomalidomide and dexamethasone, the recommended dosage of EMPLICITI in cycles 1-2 (28-day cycle) is 10 mg/kg administered intravenously (IV) once every week
- Starting at cycle 3 and onward (28-day cycle), 20 mg/kg EMPLICITI is administered intravenously once every 4 weeks
- Continue treatment until disease progression or unacceptable toxicity

Pretreatment on days that EMPLICITI is administered[6]	
3-24 hours prior	**45-90 minutes prior**
Oral dexamethasone: Patients ≤75 years old: 28 mg Patients >75 years old: 8 mg	8 mg IV dexamethasone + H_1 blocker: diphenhydramine (25-50 mg orally or IV) or equivalent + H_2 blocker + Acetaminophen (650-1000 mg orally)

Please see the EMPLICITI, pomalidomide, and dexamethasone dosing schedule on the next page.

Please refer to the EMPLICITI, pomalidomide, and dexamethasone Full Prescribing Information for additional information.

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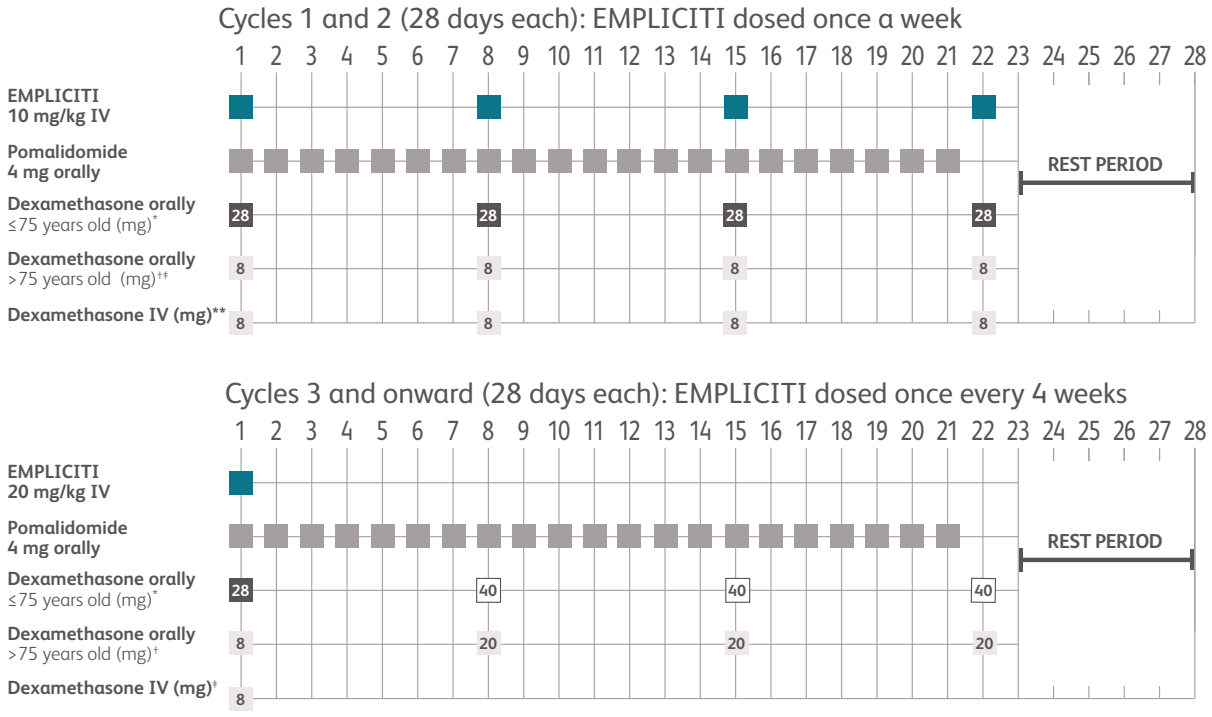
Dosing and Administration for EMPLICITI® (elotuzumab) (cont'd)

EMPLICITI dosing in combination with pomalidomide and dexamethasone[6]

EMPLICITI + pomalidomide and dexamethasone dosing schedule



On days that EMPLICITI is not administered, but a dose of dexamethasone is scheduled, (Days 8, 15 and 22 of cycle 3 and all subsequent cycles) dexamethasone 40 mg should be given orally to patients 75 years or younger and 20 mg orally to patients older than 75 years.[7]

*Oral dexamethasone (28 mg) taken between 3 and 24 hours before EMPLICITI infusion.

†Oral dexamethasone (8 mg) taken between 3 and 24 hours before EMPLICITI infusion.

‡Intravenous dexamethasone and other premedications are given 45-90 minutes prior to EMPLICITI infusion.

Please refer to the EMPLICITI, pomalidomide, and dexamethasone Full Prescribing Information for additional information.

(continued on next page)

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Dosing and Administration for EMPLICITI® (elotuzumab) (cont'd)

Important Dosing Information for POMALYST® (pomalidomide)[11]

- POMALYST may be taken with or without food on Days 1 through 21 of each 28-day cycle. Inform patients not to break, chew, or open the capsules. Swallow capsules whole with water
- Monitor CBCs every week for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification
- Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes and evaluate. After return to baseline values, treatment at a lower dose may be considered
- Reduce POMALYST dose to 3 mg orally daily in patients with mild to moderate hepatic impairment and to 2 mg in patients with severe hepatic impairment
- Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg
- Reduce POMALYST dose to 3 mg orally daily in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days

Please refer to the EMPLICITI, pomalidomide, and dexamethasone Full Prescribing Information for additional information.

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

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Determining Your Order[6]

Because dosing for EMPLICITI is weight-based, the dose of EMPLICITI will vary by patient, and may be provided through a combination of vial sizes.*

Step 1: Calculate total dose in mg needed (weight in kg x 10 = total dose in mg)

Step 2: Determine quantity of single-dose vials needed based on total dose (see table below)†

A person weighing **60 kg** would require a total dosage of **600 mg of EMPLICITI**
(two 300-mg vials)

A person weighing **91 kg** would require a total dosage of **910 mg of EMPLICITI**
(two 300-mg vials and one 400-mg vial)

A person weighing **123 kg** would require a total dosage of **1230 mg of EMPLICITI**
(three 300-mg vials and one 400-mg vial)

*EMPLICITI is supplied in 300-mg or 400-mg single-dose vials.[6]

†The calculations in the examples above are all based on 10 mg/kg doses. In dosing regimen with pomalidomide and dexamethasone, dosing for EMPLICITI is 20 mg/kg starting with cycle 3.[6]

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

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Medicare Drug Reimbursement for EMPLICITI® (elotuzumab)

What is the Medicare reimbursement allowable for EMPLICITI?

Physicians*

- The payment limit is 106% of average sales price (ASP), not including sequestration, and represents one billing unit of EMPLICITI, which is billed for each 1 mg[12†]
- The amount paid to physicians for EMPLICITI HCPCS code J9176 is published at the beginning of each calendar quarter in "Payment Allowance Limits for Medicare Part B Drugs,"[13] which can be downloaded at https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice
- Medicare Part B will pay physicians 80% of the allowed price for EMPLICITI HCPCS code J9176; the patient is responsible for 20% co-insurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)[14]

Hospital outpatient facilities*

Drugs paid for separately under the hospital outpatient fee schedule are based on 106% of average sales price (ASP), not including sequestration, for one billing unit for the corresponding HCPCS code. This is 1 mg for EMPLICITI HCPCS code J9176[12]

- The Payment Allowance Limits are published each quarter at https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice[13]

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs[15,16]
- This prospective rate changes on October 1 each year and does not allow for drugs to be paid separately[17]

*While the statutory amount that Medicare will reimburse for a Part B Drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[18]

†See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Commercial Insurance Reimbursement for EMPLICITI® (elotuzumab)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule[19]
- The fee schedules are based on the ASP or AWP, as published by a credible source,[20,21] or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R)[20-22]

Hospital outpatient facilities[21]

- In this setting, reimbursement is most commonly based on percentage of charges
- Alternatively, some hospitals use the same ASP or AWP methodologies typically used by physician offices
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge[15]
- There are private payers that pay on a version of the DRGs[16]
- There are also payers that pay on a negotiated and fixed rate per day called a "per diem"; there are capitated rates for inpatients as well[16]
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so[23]

Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab)

INDICATIONS

EMPLICITI® (elotuzumab) is indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one to three prior therapies.

EMPLICITI® (elotuzumab) is indicated in combination with POMALYST and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

REVLIMID® (lenalidomide) is a thalidomide analogue indicated for the treatment of adult patients with multiple myeloma (MM) in combination with dexamethasone (dex).

REVLIMID is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).

REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

POMALYST® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for adult patients with MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

REVLIMID & POMALYST Boxed WARNINGS

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS AND ARTERIAL THROMBOEMBOLISM

EMBRYO-FETAL TOXICITY: REVLIMID & POMALYST are thalidomide analogues and are contraindicated in pregnancy. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting treatment and use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment. To avoid embryo-fetal exposure, REVLIMID and POMALYST are only available through their respective restricted distribution programs, Lenalidomide REMS and POMALYST REMS®.

Information about the Lenalidomide REMS program is available at www.lenalidomiderems.com or by calling 1-888-423-5436 and POMALYST REMS program is available at www.pomalystrems.com or by calling 1-888-423-5436.

HEMATOLOGIC TOXICITY: REVLIMID can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS had to have a dose delay/reduction during the major study. Thirty-four percent of patients had to have a second dose delay/reduction. Grade 3 or 4 hematologic toxicity was seen in 80% of patients enrolled in the study. Patients on therapy for del 5q MDS should have their complete blood counts monitored weekly for the first 8 weeks of therapy and at least monthly thereafter. Patients may require dose interruption and/or reduction. Patients may require use of blood product support and/or growth factors.

VENOUS AND ARTERIAL THROMBOEMBOLISM: REVLIMID & POMALYST have demonstrated a significantly increased risk of deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke in patients with MM. Thromboprophylaxis is recommended and the choice of regimen should be based on assessment of the patient's underlying risk factors. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling.

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Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

CONTRAINDICATIONS

Pregnancy: **See Boxed WARNINGS**. REVLIMID & POMALYST can cause fetal harm when administered to a pregnant female and are contraindicated in females who are pregnant. If the patient becomes pregnant while taking REVLIMID or POMALYST, the patient should be apprised of the potential risk to the fetus.

Severe Hypersensitivity Reactions: REVLIMID & POMALYST are contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis) to lenalidomide, pomalidomide, or any of the excipients.

REVLIMID, POMALYST & EMPLICITI WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity & Females of Reproductive Potential: **See Boxed WARNINGS**. Females of reproductive potential must avoid pregnancy for at least 4 weeks before beginning REVLIMID or POMALYST.

- Males: REVLIMID & POMALYST are present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking REVLIMID or POMALYST even if they have undergone a successful vasectomy. This protective measure must be followed for up to 4 weeks after discontinuing REVLIMID or POMALYST. Males must not donate sperm while taking REVLIMID and for up to 4 weeks after discontinuing REVLIMID, or while taking POMALYST.
- Blood Donation: Patients must not donate blood during treatment with REVLIMID or POMALYST and for 4 weeks following discontinuation of the drug, as the blood might be given to a pregnant female patient whose fetus must not be exposed to REVLIMID or POMALYST.

REMS Program: **See Boxed WARNINGS.** Prescribers and pharmacies must be certified with the respective **Lenalidomide** or **POMALYST REMS** program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive REVLIMID or POMALYST. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.

- Further information about the **POMALYST REMS** program is available at **www.pomalystrems.com** or by telephone at 1-888-423-5436.
- Further information about the **Lenalidomide REMS** program is available at **www.lenalidomiderems.com** or by telephone at 1-888-423-5436.

Hematologic Toxicity: REVLIMID & POMALYST can cause significant neutropenia and thrombocytopenia. Neutropenia, anemia, and thrombocytopenia were the most frequently reported Grade 3 or 4 adverse reactions in patients taking REVLIMID & POMALYST in clinical trials. Patients may require dose interruption and/or modification. For REVLIMID, monitor patients with neutropenia for signs of infection and advise patients to observe for bleeding or bruising, especially with use of concomitant medications that may increase risk of bleeding. Monitor complete blood counts (CBC) every 7 days for the first 2 cycles, on days 1 and 15 of cycle 3, and every 28 days thereafter. For POMALYST, monitor CBC weekly for the first 8 weeks and monthly thereafter.

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Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

Venous & Arterial Thromboembolism: **See Boxed WARNINGS.** Venous thromboembolic events (DVT and PE) and arterial thromboses (myocardial infarction [MI] and stroke [CVA]) are increased in patients treated with REVLIMID or POMALYST. Thromboprophylaxis is recommended and the regimen should be based on the patient's underlying risks. Patients with known risk factors, including prior thrombosis, may be at greater risk, and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Erythropoietin-stimulating agents (ESAs) and estrogens may further increase the risk of thrombosis when used with REVLIMID and their use should be based on a benefit-risk decision.

Increased Mortality in Patients With CLL: In a clinical trial in the first line treatment of patients with CLL, single-agent REVLIMID therapy increased the risk of death as compared to single-agent chlorambucil. Serious adverse cardiovascular reactions, including atrial fibrillation, myocardial infarction, and cardiac failure, occurred more frequently in the REVLIMID arm. REVLIMID is not indicated and not recommended for use in CLL outside of controlled clinical trials.

Second Primary Malignancies (SPM): In clinical trials in patients with MM receiving REVLIMID, and in patients with FL or MZL receiving REVLIMID + rituximab therapy, an increase of hematologic plus solid tumor SPM, notably AML, have been observed. In patients with MM, MDS was also observed. In patients taking REVLIMID, monitor for the development of SPM and take into account both the potential benefit of REVLIMID and risk of SPM when considering treatment. In patients receiving POMALYST as an investigational therapy outside of MM, cases of AML have been reported.

In the EMPLICITI ELOQUENT-2 trial (N=635), invasive second primary malignancies (SPM) were 9% (ERd) and 6% (Rd). The rate of hematologic malignancies was the same between ERd and Rd treatment arms (1.6%). Solid tumors were reported in 3.5% (ERd) and 2.2% (Rd). Skin cancer was reported in 4.4% (ERd) and 2.8% (Rd). In the ELOQUENT-3 trial (N=115), invasive SPMs were 0% (EPd) and 1.8% (Pd). Monitor patients for the development of SPMs.

Increased Mortality With Pembrolizumab: In clinical trials in patients with MM, the addition of pembrolizumab to a thalidomide analogue (REVLIMID or POMALYST) plus dexamethasone resulted in increased mortality. Treatment of patients with MM with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Hepatotoxicity: Hepatic failure, including fatal cases, have occurred in patients treated with REVLIMID + dexamethasone and POMALYST. Elevated levels of alanine aminotransferase and bilirubin have also been observed in patients treated with POMALYST. Monitor liver function tests monthly for POMALYST, and periodically for REVLIMID. Stop REVLIMID or POMALYST upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

In the ELOQUENT-2 trial (EMPLICITI + REVLIMID + dexamethasone vs REVLIMID + dexamethasone) (N=635), AST/ALT >3X the upper limit, total bilirubin >2X the upper limit, and alkaline phosphatase <2X the upper limit were 2.5% (EMPLICITI arm) vs 0.6% (control arm). Of 8 patients experiencing hepatotoxicity, 2 patients discontinued treatment while 6 patients had resolution and continued. Stop EMPLICITI upon ≥Grade 3 elevation of liver enzymes. Continuation of treatment may be considered after return to baseline values.

Infusion Reactions: Infusion reactions were reported in 10% of patients treated with EMPLICITI in the ELOQUENT-2 trial [EMPLICITI + REVLIMID + dexamethasone (ERd) vs REVLIMID + dexamethasone (Rd)] and 3.3% in the ELOQUENT-3 trial [EMPLICITI + POMALYST + dexamethasone (EPd) vs POMALYST + dexamethasone (Pd)]. In the ELOQUENT-2 trial, all infusion

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Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

reactions were Grade 3 or lower, with Grade 3 infusion reactions occurring in 1% of patients. The most common symptoms included fever, chills, and hypertension. Bradycardia and hypotension also developed during infusions. In the trial, 5% of patients required interruption of the administration of EMPLICITI for a median of 25 minutes due to infusion reactions, and 1% of patients discontinued due to infusion reactions. Of the patients who experienced an infusion reaction, 70% (23/33) had them during the first dose. In the ELOQUENT-3 trial, the only infusion reaction symptom was chest discomfort (2%), which was Grade 1. All the patients who experienced an infusion reaction had them during the first treatment cycle.

- If a Grade 2 or higher infusion reaction occurs, interrupt the EMPLICITI infusion and institute appropriate medical and supportive measures. If the infusion reaction recurs, stop the EMPLICITI infusion and do not restart it on that day. Severe infusion reactions may require permanent discontinuation of EMPLICITI therapy and emergency treatment.
- Premedicate with dexamethasone, H1 blocker, H2 blocker, and acetaminophen prior to EMPLICITI infusion.

Infections: In the ELOQUENT-2 trial (N=635), infections were reported in 81% of patients in the ERd arm and 74% in the Rd arm. Grade 3-4 infections were 28% (ERd) and 24% (Rd). Discontinuations due to infections were 3.5% (ERd) and 4.1% (Rd). Fatal infections were 2.5% (ERd) and 2.2% (Rd). Opportunistic infections were reported in 22% (ERd) and 13% (Rd). Fungal infections were 10% (ERd) and 5% (Rd). Herpes zoster was 14% (ERd) and 7% (Rd). In the ELOQUENT-3 trial (N=115), infections were reported in 65% of patients in both the EPd arm and the Pd arm. Grade 3-4 infections were reported in 13% (EPd) and 22% (Pd). Discontinuations due to infections were 7% (EPd) and 5% (Pd). Fatal infections were 5% (EPd) and 3.6% (Pd). Opportunistic infections were reported in 10% (EPd) and 9% (Pd). Herpes zoster was reported in 5% (EPd) and 1.8% (Pd). Monitor patients for development of infections and treat promptly.

Severe Cutaneous Reactions: Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with REVLIMID & POMALYST. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. These reactions can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive REVLIMID. Consider REVLIMID & POMALYST interruption or discontinuation for Grade 2 or 3 skin rash. Permanently discontinue REVLIMID & POMALYST for Grade 4 rash, exfoliative or bullous rash, or for other severe cutaneous reactions such as SJS, TEN, or DRESS.

Tumor Lysis Syndrome (TLS): TLS may occur in patients treated with REVLIMID or POMALYST. Fatal instances of TLS have been reported during treatment with REVLIMID. Closely monitor patients at risk and take appropriate preventive approaches.

Hypersensitivity: Hypersensitivity including angioedema, anaphylaxis, and anaphylactic reactions to REVLIMID & POMALYST have been reported. Permanently discontinue REVLIMID & POMALYST for angioedema or anaphylaxis.

Dizziness & Confusional State: In patients taking POMALYST in clinical trials, 14% experienced dizziness (1% Grade 3 or 4) and 7% a confusional state (3% Grade 3 or 4). Instruct patients to avoid situations where dizziness or confusional state may be a problem and not to take other medications that may cause dizziness or confusional state without adequate medical advice.

Neuropathy: In patients taking POMALYST in clinical trials, 18% experienced neuropathy (2% Grade 3 in one trial) and 12% peripheral neuropathy.

Tumor Flare Reaction (TFR): Serious tumor flare reactions, including fatal reactions, have occurred during investigational use of REVLIMID for CLL and lymphoma. Monitor and evaluation for TFR is recommended in patients with MCL, FL, or MZL.

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Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

Impaired Stem Cell Mobilization: A decrease in the number of CD34+ cells collected after treatment (>4 cycles) with REVLIMID has been reported. Consider early referral to transplant center to optimize timing of the stem cell collection.

Thyroid Disorders: Both hypothyroidism and hyperthyroidism have been reported. Measure thyroid function before starting REVLIMID treatment and during therapy.

Early Mortality in Patients With MCL: In another MCL study, there was an increase in early deaths (within 20 weeks); 12.9% in the REVLIMID arm versus 7.1% in the control arm. Risk factors for early deaths include high tumor burden, MIPI score at diagnosis, and high WBC at baseline (≥10 x 10^9/L).

Interference with Determination of Complete Response: EMPLICITI is a humanized IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis and immunofixation assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and possibly relapse from complete response in patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

REVLIMID - Multiple Myeloma

- **In Newly Diagnosed**: The most frequently reported Grade 3 or 4 reactions included neutropenia, anemia, thrombocytopenia, pneumonia, asthenia, fatigue, back pain, hypokalemia, rash, cataract, lymphopenia, dyspnea, DVT, hyperglycemia, and leukopenia. The highest frequency of infections occurred in Arm Rd Continuous (75%) compared to Arm MPT (56%). There were more Grade 3 and 4 and serious adverse reactions of infection in Arm Rd Continuous than either Arm MPT or Rd18.
  - The most common adverse reactions reported in ≥20% (Arm Rd Continuous): diarrhea (45%), anemia (44%), neutropenia (35%), fatigue (33%), back pain (32%), asthenia (28%), insomnia (28%), rash (26%), decreased appetite (23%), cough (23%), dyspnea (22%), pyrexia (21%), abdominal pain (20%), muscle spasms (20%), and thrombocytopenia (20%).
- **Maintenance Therapy Post Auto-HSCT**: The most frequently reported Grade 3 or 4 reactions in ≥20% (REVLIMID arm) included neutropenia, thrombocytopenia, and leukopenia. The serious adverse reactions of lung infection and neutropenia (more than 4.5%) occurred in the REVLIMID arm.
  - The most frequently reported adverse reactions in ≥20% (REVLIMID arm) across both maintenance studies (Study 1, Study 2) were neutropenia (79%, 61%), thrombocytopenia (72%, 24%), leukopenia (23%, 32%), anemia (21%, 9%), upper respiratory tract infection (27%, 11%), bronchitis (4%, 47%), nasopharyngitis (2%, 35%), cough (10%, 27%), gastroenteritis (0%, 23%), diarrhea (54%, 39%), rash (32%, 8%), fatigue (23%, 11%), asthenia (0%, 30%), muscle spasm (0%, 33%), and pyrexia (8%, 20%).
- **After at Least One Prior Therapy**: The most common adverse reactions reported in ≥20% (REVLIMID/dex vs dex/placebo): fatigue (44% vs 42%), neutropenia (42% vs 6%), constipation (41% vs 21%), diarrhea (39% vs 27%), muscle cramp (33% vs 21%), anemia (31% vs 24%), pyrexia (27% vs 23%), peripheral edema (26% vs 21%), nausea (26% vs 21%), back pain (26% vs 19%), upper respiratory tract infection (25% vs 16%), dyspnea (24% vs 17%), dizziness (23% vs 17%), thrombocytopenia (22% vs 11%), rash (21% vs 9%), tremor (21% vs 7%), and weight decreased (20% vs 15%).

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Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

POMALYST

- The most common adverse reactions for POMALYST (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.
- In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥2% higher than control) included neutropenia (51%), fatigue and asthenia (47%), upper respiratory tract infection (31%), thrombocytopenia (30%), pyrexia (27%), dyspnea (25%), diarrhea (22%), constipation (22%), back pain (20%), cough (20%), pneumonia (19%), bone pain (18%), edema peripheral (17%), peripheral neuropathy (17%), muscle spasms (15%), and nausea (15%). Grade 3 or 4 adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥1% higher than control) included neutropenia (48%), thrombocytopenia (22%), and pneumonia (16%).

EMPLICITI

- ELOQUENT-2 trial: Serious adverse reactions were 65% (ERd) and 57% (Rd). The most frequent serious adverse reactions in the ERd arm compared to the Rd arm were: pneumonia (15%, 11%), pyrexia (7%, 5%), respiratory tract infection (3.1%, 1.3%), anemia (2.8%, 1.9%), pulmonary embolism (3.1%, 2.5%), and acute renal failure (2.5%, 1.9%). The most common adverse reactions in ERd and Rd, respectively (≥20%) were fatigue (62%, 52%), diarrhea (47%, 36%), pyrexia (37%, 25%), constipation (36%, 27%), cough (34%, 19%), peripheral neuropathy (27%, 21%), nasopharyngitis (25%, 19%), upper respiratory tract infection (23%, 17%), decreased appetite (21%, 13%), and pneumonia (20%, 14%).
- ELOQUENT-3 trial: Serious adverse reactions were 70% (EPd) and 60% (Pd). The most frequent serious adverse reactions in the EPd arm compared to the Pd arm were: pneumonia (13%, 11%) and respiratory tract infection (7%, 3.6%). The most common adverse reactions in EPd arm (≥20% EPd) and Pd, respectively, were constipation (22%, 11%) and hyperglycemia (20%, 15%).

DRUG INTERACTIONS

- **REVLIMID**: Periodically monitor digoxin plasma levels due to increased C_{max} and AUC with concomitant REVLIMID therapy. Patients taking concomitant therapies such as ESAs or estrogen-containing therapies may have an increased risk of thrombosis. It is not known whether there is an interaction between dexamethasone and warfarin. Close monitoring of PT and INR is recommended in patients with MM taking concomitant warfarin.
- **POMALYST**: Avoid concomitant use with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.

USE IN SPECIFIC POPULATIONS

- **Pregnancy**: **See Boxed WARNINGS for REVLIMID & POMALYST**. If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There are REVLIMID and POMALYST pregnancy exposure registries that monitor pregnancy outcomes in females exposed to REVLIMID or POMALYST during pregnancy as well as female partners of male patients who are exposed to REVLIMID or POMALYST. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure of the drug to the FDA via the MedWatch program at 1-800-FDA-1088 and also to REMS Call Center at 1-888-423-5436.

(continued on next page)

Please see US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST® (pomalidomide), and REVLIMID® (lenalidomide), including **Boxed WARNINGS** for POMALYST and REVLIMID.

For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday, or visit www.BMSAccessSupport.com.

Important Safety Information for REVLIMID® (lenalidomide), POMALYST® (pomalidomide), & EMPLICITI® (elotuzumab) (cont'd)

- **Pregnancy and EMPLICITI Use**: There are no available data on EMPLICITI use in pregnant women to inform a drug-associated risk of major defects and miscarriage.
- **Lactation**: There is no information regarding the presence of pomalidomide, lenalidomide or elotuzumab in human milk, the effects of POMALYST, REVLIMID or EMPLICITI on the breastfed child, or the effects of POMALYST, REVLIMID or EMPLICITI on milk production. Pomalidomide was excreted in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for adverse reactions in a breastfed child from POMALYST or REVLIMID, advise women not to breastfeed during treatment.
- **Pediatric Use**: Safety and effectiveness of REVLIMID, POMALYST or in combination with EMPLICITI have not been established in pediatric patients.
- **Geriatric Use**: No dose adjustment is required for POMALYST based on age. Patients >65 years of age were more likely than patients ≤65 years of age to experience pneumonia.
- **Renal Impairment**: Adjust the starting dose of REVLIMID based on the creatinine clearance value and for patients on dialysis. For POMALYST in patients with severe renal impairment requiring dialysis, reduce the recommended dosage to 3 mg orally daily. Take dose of POMALYST following hemodialysis on hemodialysis days.
- **Hepatic Impairment**: In patients with mild to moderate hepatic impairment, reduce POMALYST dosage to 3 mg orally daily and to 2 mg orally daily in patients with severe hepatic impairment.
- **Smoking Tobacco**: Advise patients that smoking may reduce the efficacy of POMALYST. Cigarette smoking reduces pomalidomide AUC due to CYP1A2 induction.

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Please see Important Safety Information, including **Boxed WARNINGS** for POMALYST® (pomalidomide) and REVLIMID® (lenalidomide), on pages 21-27, and US Full Prescribing Information for EMPLICITI® (elotuzumab), POMALYST, and REVLIMID.

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