



INDICATIONS

CIMERLI® (ranibizumab-eqrn) is indicated for the treatment of patients with:

- Neovascular (wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)
- Myopic Choroidal Neovascularization (mCNV)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: CIMERLI® is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in CIMERLI®. Hypersensitivity reactions may manifest as severe intraocular inflammation.



Diagnosis Codes (ICD-10-CM codes) will vary based on clinical diagnosis and payer requirements. The following tables list diagnosis codes that align with the FDA-approved indications for CIMERLI® but may not be all-inclusive. Clinical judgement should be used to determine the most appropriate codes. Please confirm coding requirements with each payer for each patient prior to drug administration.

The coding information contained herein is for informational purposes only and is not a guarantee of coverage or reimbursement for any product or service.

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CIMERLI Coding Snapshot

| HCPCS Code* | Description |
|-------------------------|------------------------------------------------------------------------------------------------------------------------|
| Q5128 | Injection, ranibizumab-eqrn (CIMERLI), biosimilar, 0.1 mg |
| Ť | MERLI administered on or after 4/1/2023. 4/1/2023, please use the appropriate miscellaneous code. |
| Billable Units | Example |
| 0.1 mg | 0.5 mg = 5 billable units 0.3 mg = 3 billable units |
| HCPCS Modifier | Description |
| JZ | Zero drug amount discarded/not administered to any patient (New modifier to indicate administration of the full vial.) |
| CPT Codes | Description |
| 67028 | Intravitreal injection of a pharmacologic agent (separate procedure) |
| CPT Modifier | Description |
| -LT | Left eye modifier |
| -RT | Right eye modifier |
| -50 | Bilateral |
| Patient Diagnosis Codes | Description |
| ICD-10-CM | ICD-10 codes vary by patient diagnosis |
| NDC | Description |
| 61314-0625-94 | 0.5 mg/0.05 mL (10 mg/mL) vial (one carton) |
| 61314-0624-94 | 0.3 mg/0.05 mL (6 mg/mL) vial (one carton) |

The coding information contained herein is for informational purposes only and is not a guarantee of coverage or reimbursement for any product or service. This information is not intended to substitute for the physician's independent diagnosis or treatment of each patient.



WET AGE-RELATED MACULAR DEGENERATION (wet AMD)

For additional information:



Visit CIMERLI.com



Call 1-844-4SANDOZ (1-844-472-6369)



Contact your CIMERLI Sales Representative or Field Reimbursement Manager

Diagnosis Codes (ICD-10-CM codes) will vary based on clinical diagnosis and payer requirements. The following tables list diagnosis codes that align with the FDA-approved indications for CIMERLI® but may not be all-inclusive. Clinical judgement should be used to determine the most appropriate codes. Please confirm coding requirements with each payer for each patient prior to drug administration.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachments: Intravitreal injections, including those
with ranibizumab products, have been associated with endophthalmitis, retinal
detachment, and iatrogenic traumatic cataract. Proper aseptic injection technique
should always be utilized when administering CIMERLI®. In addition, patients
should be monitored following the injection to permit early treatment, should an
infection occur

WET AGE-RELATED MACULAR DEGENERATION (WET AMD)

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------|
| H35.3210 | Exudative age-related macular degeneration, right eye, stage unspecified |
| H35.3211 | Exudative age-related macular degeneration, right eye, with active choroidal neovascularization |
| H35.3212 | Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization |
| H35.3213 | Exudative age-related macular degeneration, right eye, with inactive scar |
| H35.3220 | Exudative age-related macular degeneration, left eye, stage unspecified |
| H35.3221 | Exudative age-related macular degeneration, left eye, with active choroidal neovascularization |
| H35.3222 | Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization |
| H35.3223 | Exudative age-related macular degeneration, left eye, with inactive scar |
| H35.3230 | Exudative age-related macular degeneration, bilateral, stage unspecified |
| H35.3231 | Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization |
| H35.3232 | Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization |
| H35.3233 | Exudative age-related macular degeneration, left eye, with inactive scar |
| H35.3290 | Exudative age-related macular degeneration, unspecified eye, stage unspecified |
| H35.3291 | Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization |
| H35.3292 | Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization |
| H35.81 | Retinal edema |

WARNINGS AND PRECAUTIONS (continued)

- Increases in Intraocular Pressure: Increases in intraocular pressure have been noted both pre-injection and post-injection (at 60 minutes) while being treated with ranibizumab products. Monitor intraocular pressure prior to and following intravitreal injection with CIMERLI® and manage appropriately
- Thromboembolic Events: Although there was a low rate of arterial thromboembolic events
 (ATEs) observed in the ranibizumab clinical trials, there is a potential risk of ATEs following
 intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial
 infarction, or vascular death (including deaths of unknown cause)



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Diagnosis Codes (ICD-10-CM codes) will vary based on clinical diagnosis and payer requirements. The following tables list diagnosis codes that align with the FDA-approved indications for CIMERLI® but may not be all-inclusive. Clinical judgement should be used to determine the most appropriate codes. Please confirm coding requirements with each payer for each patient prior to drug administration.

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WARNINGS AND PRECAUTIONS (continued)

Neovascular (Wet) Age-Related Macular Degeneration (wAMD)

• The ATE rate in the three controlled neovascular AMD studies (AMD-1, AMD-2, AMD-3) during the first year was 1.9% (17 of 874) in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab compared with 1.1% (5 of 441) in patients from the control arms. In the second year of Studies AMD-1 and AMD-2, the ATE rate was 2.6% (19 of 721) in the combined group of ranibizumab-treated patients compared with 2.9% (10 of 344) in patients from the control arms. In Study AMD-4, the ATE rates observed in the 0.5 mg arms during the first and second year were similar to rates observed in Studies AMD-1, AMD-2, and AMD-3

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------|
| E08.311 | Diabetes due to underlying condition with unspecified diabetic retinopathy with macular edema |
| E08.3211 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3212 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3213 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3219 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3311 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3312 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3313 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3319 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3411 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3412 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3413 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3419 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3511 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye |
| E08.3512 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye |

WARNINGS AND PRECAUTIONS (continued)

Neovascular (Wet) Age-Related Macular Degeneration (wAMD) (continued)

• In a pooled analysis of 2-year controlled studies (AMD-1, AMD-2, and a study of ranibizumab used adjunctively with verteporfin photodynamic therapy), the stroke rate (including both ischemic and hemorrhagic stroke) was 2.7% (13 of 484) in patients treated with 0.5 mg ranibizumab compared to 1.1% (5 of 435) in patients in the control arms (odds ratio 2.2 [95% confidence interval (0.8-7.1)])

| ICD-10-CM | Description |
|-----------|------------------------------------------------------------------------------------------------------------------------------------|
| E08.3513 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral |
| E08.3519 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.311 | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E09.3211 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E09.3212 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3213 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E09.3219 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3311 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E09.3312 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3313 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E09.3319 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3411 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E09.3412 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3413 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E09.3419 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3511 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |

WARNINGS AND PRECAUTIONS (continued)

Macular Edema Following Retinal Vein Occlusion (RVO)

The ATE rate in the two controlled RVO studies during the first 6 months was 0.8% in both
the ranibizumab and control arms of the studies (4 of 525 in the combined group of patients
treated with 0.3 mg or 0.5 mg ranibizumab and 2 of 260 in the control arms). The stroke rate
was 0.2% (1 of 525) in the combined group of ranibizumab-treated patients compared to 0.4%
(1 of 260) in the control arms

| ICD-10-CM | Description |
|-----------|------------------------------------------------------------------------------------------------------------------------|
| E09.3512 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E09.3513 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E09.3519 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.311 | Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E10.3211 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3212 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3213 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3311 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3312 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3313 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3411 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3412 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3413 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |

WARNINGS AND PRECAUTIONS (continued)

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

• In a pooled analysis of Studies D-1 and D-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg ranibizumab, 5.6% (14 of 250) with 0.3 mg ranibizumab, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg ranibizumab, 1.2% (3 of 250) with 0.3 mg ranibizumab, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg ranibizumab and 10.8% (27 of 250) with 0.3 mg ranibizumab; the stroke rate was 4.8% (12 of 249) with 0.5 mg ranibizumab and 2.0% (5 of 250) with 0.3 mg ranibizumab

| ICD-10-CM | Description |
|-----------|----------------------------------------------------------------------------------------------------------------|
| E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3511 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E10.3512 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E10.3513 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.311 | Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E11.3211 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3212 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |

WARNINGS AND PRECAUTIONS (continued)

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) (continued)

• Fatal events occurred more frequently in patients with DME and DR at baseline: A pooled analysis of Studies D-1 and D-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg ranibizumab, in 2.8% (7 of 250) of patients treated with 0.3 mg ranibizumab, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg ranibizumab and in 4.4% (11 of 250) of patients treated with 0.3 mg ranibizumab. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded

| ICD-10-CM | Description |
|-----------|------------------------------------------------------------------------------------------------------------------|
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3313 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3411 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3213 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3412 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3413 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3511 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E11.3512 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E11.3513 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.311 | Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E13.3211 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3212 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |

WARNINGS AND PRECAUTIONS (continued)

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) (continued)

Retinal vasculitis with or without occlusion, typically in the presence of preexisting intraocular
inflammation or post-treatment with other intravitreal agents, have been reported with the use
of ranibizumab products. Discontinue treatment with CIMERLI® in patients who develop these
events. Patients should be instructed to report any change in vision without delay

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------------|
| E13.3219 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3311 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3312 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E13.3313 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E13.3319 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3413 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E13.3411 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3412 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E13.3419 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3511 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E13.3512 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E13.3513 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E13.3519 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |

ADVERSE REACTIONS

 Serious adverse reactions related to the injection procedure that occurred in <0.1% of intravitreal injections, including endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract



MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO)

For additional information:



Visit CIMERLI.com



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ADVERSE REACTIONS (continued)

 The most frequently reported ocular adverse reactions in ranibizumab-treated patients compared with the control group were conjunctival hemorrhage, eye pain, vitreous floaters, and increased intraocular pressure. The most common non-ocular adverse reactions were nasopharyngitis, anemia, nausea, and cough

MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO)

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------|
| H34.8110 | Central retinal vein occlusion, right eye, with macular edema |
| H34.8111 | Central retinal vein occlusion, right eye, with retinal neovascularization |
| H34.8112 | Central retinal vein occlusion, right eye, stable |
| H34.8120 | Central retinal vein occlusion, left eye, with macular edema |
| H34.8121 | Central retinal vein occlusion, left eye, with retinal neovascularization |
| H34.8122 | Central retinal vein occlusion, left eye, stable |
| H34.8130 | Central retinal vein occlusion, bilateral, with macular edema |
| H34.8131 | Central retinal vein occlusion, bilateral, with retinal neovascularization |
| H34.8132 | Central retinal vein occlusion, bilateral, stable |
| H34.8190 | Central retinal vein occlusion, unspecified eye, with macular edema |
| H34.8310 | Tributary (branch) retinal vein occlusion, right eye, with macular edema |
| H34.8311 | Tributary (branch) retinal vein occlusion, right eye, with retinal neovascularization |
| H34.8312 | Tributary (branch) retinal vein occlusion, right eye, stable |
| H34.8320 | Tributary (branch) retinal vein occlusion, left eye, with macular edema |
| H34.8321 | Tributary (branch) retinal vein occlusion, left eye, with retinal neovascularization |
| H34.8322 | Tributary (branch) retinal vein occlusion, left eye, stable |
| H34.8330 | Tributary (branch) retinal vein occlusion, bilateral, with macular edema |
| H34.8331 | Tributary (branch) retinal vein occlusion, bilateral, with retinal neovascularization |
| H34.8332 | Tributary (branch) retinal vein occlusion, bilateral, stable |
| H34.8390 | Tributary (branch) retinal vein occlusion, unspecified eye, with macular edema |
| H35.051 | Retinal neovascularization, unspecified, right eye |
| H35.052 | Retinal neovascularization, unspecified, left eye |
| H35.053 | Retinal neovascularization, unspecified, bilateral |

ADVERSE REACTIONS (continued)

 As with all therapeutic proteins, there is the potential for an immune response in patients treated with ranibizumab products. The clinical significance of immunoreactivity to ranibizumab products is unclear at this time



DIABETIC RETINOPATHY (DR)

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Postmarketing Experience

The following adverse reaction has been identified during post-approval use of ranibizumab products:

Ocular: Tear of retinal pigment epithelium among patients with neovascular AMD

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz, Inc at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

| ICD-10-CM | Description |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------|
| E08.311 | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema |
| E08.319 | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema |
| E08.3211 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3212 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3213 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3219 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3291 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye |
| E08.3292 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E08.3293 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E08.3299 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E08.3311 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3312 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3313 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3319 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3391 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E08.3392 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E08.3393 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E08.3399 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| ICD-10-CM | Description |

CONTRAINDICATIONS

CIMERLI® (ranibizumab-eqrn) is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in CIMERLI®. Hypersensitivity reactions may manifest as severe intraocular inflammation.

| ICD-10-CM | Description |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E08.3411 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E08.3412 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E08.3413 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E08.3419 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3491 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye |
| E08.3492 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E08.3493 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E08.3499 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E08.3511 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye |
| E08.3512 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye |
| E08.3513 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral |
| E08.3519 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3521 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E08.3522 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E08.3523 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |
| E08.3529 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E08.3531 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E08.3532 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |

WARNINGS AND PRECAUTIONS

• Endophthalmitis and Retinal Detachments: Intravitreal injections, including those with ranibizumab products, have been associated with endophthalmitis, retinal detachment, and iatrogenic traumatic cataract. Proper aseptic injection technique should always be utilized when administering CIMERLI®. In addition, patients should be monitored following the injection to permit early treatment, should an infection occur

| ICD-10-CM | Description |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E08.3533 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E08.3539 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |
| E08.3541 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E08.3542 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |
| E08.3543 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E08.3549 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E08.3551 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, right eye |
| E08.3552 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, left eye |
| E08.3553 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, bilateral |
| E08.3559 | Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, unspecified eye |
| E08.3591 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye |
| E08.3592 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye |
| E08.3593 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral |
| E08.3599 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, unspecified eye |
| E09.311 | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E09.319 | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy without macular edema |
| E09.3211 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |

• Increases in Intraocular Pressure: Increases in intraocular pressure have been noted both pre-injection and post-injection (at 60 minutes) while being treated with ranibizumab products. Monitor intraocular pressure prior to and following intravitreal injection with CIMERLI® and manage appropriately

DIABETIC RETINOPATHY (DR)

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------|
| E09.3212 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3213 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E09.3219 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3291 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |
| E09.3292 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E09.3293 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E09.3299 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E09.3311 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E09.3312 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3313 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E09.3319 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3391 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E09.3392 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E09.3393 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E09.3399 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E09.3411 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E09.3412 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E09.3413 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |

WARNINGS AND PRECAUTIONS (continued)

Thromboembolic Events: Although there was a low rate of arterial thromboembolic events
(ATEs) observed in the ranibizumab clinical trials, there is a potential risk of ATEs following
intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial
infarction, or vascular death (including deaths of unknown cause)

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E09.3419 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3491 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye |
| E09.3492 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E09.3493 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E09.3499 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E09.3511 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E09.3512 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E09.3513 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E09.3519 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3521 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E09.3522 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E09.3523 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |
| E09.3529 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E09.3531 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E09.3532 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |
| E09.3533 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E09.3539 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |

Neovascular (Wet) Age-Related Macular Degeneration (wAMD)

• The ATE rate in the three controlled neovascular AMD studies (AMD-1, AMD-2, AMD-3) during the first year was 1.9% (17 of 874) in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab compared with 1.1% (5 of 441) in patients from the control arms. In the second year of Studies AMD-1 and AMD-2, the ATE rate was 2.6% (19 of 721) in the combined group of ranibizumab-treated patients compared with 2.9% (10 of 344) in patients from the control arms. In Study AMD-4, the ATE rates observed in the 0.5 mg arms during the first and second year were similar to rates observed in Studies AMD-1, AMD-2, and AMD-3

| ICD-10-CM | Description |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E09.3541 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E09.3542 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |
| E09.3543 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E09.3549 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E09.3551 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, right eye |
| E09.3552 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, left eye |
| E09.3553 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, bilateral |
| E09.3559 | Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |
| E09.3591 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye |
| E09.3592 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye |
| E09.3593 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral |
| E09.3599 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.311 | Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E10.319 | Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema |
| E10.3211 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3212 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3213 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |

Neovascular (Wet) Age-Related Macular Degeneration (wAMD) (continued)

• In a pooled analysis of 2-year controlled studies (AMD-1, AMD-2, and a study of ranibizumab used adjunctively with verteporfin photodynamic therapy), the stroke rate (including both ischemic and hemorrhagic stroke) was 2.7% (13 of 484) in patients treated with 0.5 mg ranibizumab compared to 1.1% (5 of 435) in patients in the control arms (odds ratio 2.2 [95% confidence interval (0.8-7.1)])

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------|
| E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3291 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |
| E10.3292 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E10.3293 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E10.3299 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3311 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3312 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3313 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3391 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E10.3392 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E10.3393 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E10.3399 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3411 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E10.3412 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E10.3413 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3491 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye |

Macular Edema Following Retinal Vein Occlusion (RVO)

• The ATE rate in the two controlled RVO studies during the first 6 months was 0.8% in both the ranibizumab and control arms of the studies (4 of 525 in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab and 2 of 260 in the control arms). The stroke rate was 0.2% (1 of 525) in the combined group of ranibizumab-treated patients compared to 0.4% (1 of 260) in the control arms

| ICD-10-CM | Description |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E10.3492 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E10.3493 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E10.3499 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E10.3511 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E10.3512 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E10.3513 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E10.3521 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E10.3522 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E10.3523 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |
| E10.3529 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E10.3531 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E10.3532 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |
| E10.3533 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E10.3539 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |
| E10.3541 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E10.3542 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

• In a pooled analysis of Studies D-1 and D-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg ranibizumab, 5.6% (14 of 250) with 0.3 mg ranibizumab, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg ranibizumab, 1.2% (3 of 250) with 0.3 mg ranibizumab, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg ranibizumab and 10.8% (27 of 250) with 0.3 mg ranibizumab; the stroke rate was 4.8% (12 of 249) with 0.5 mg ranibizumab and 2.0% (5 of 250) with 0.3 mg ranibizumab

| ICD-10-CM | Description |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E10.3543 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E10.3549 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E10.3551 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye |
| E10.3552 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye |
| E10.3553 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral |
| E10.3559 | Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |
| E10.3591 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye |
| E10.3592 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye |
| E10.3593 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral |
| E10.3599 | Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.311 | Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E11.319 | Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema |
| E11.3211 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3212 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3291 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) (continued)

• Fatal events occurred more frequently in patients with DME and DR at baseline: A pooled analysis of Studies D-1 and D-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg ranibizumab, in 2.8% (7 of 250) of patients treated with 0.3 mg ranibizumab, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg ranibizumab and in 4.4% (11 of 250) of patients treated with 0.3 mg ranibizumab. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded

| ICD-10-CM | Description |
|-----------|---------------------------------------------------------------------------------------------------------------------|
| E11.3292 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3293 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E11.3299 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3313 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3391 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E11.3392 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3393 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E11.3399 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3411 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E11.3412 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E11.3413 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3491 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye |
| E11.3492 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E11.3493 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |

Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) (continued)

Retinal vasculitis with or without occlusion, typically in the presence of preexisting
intraocular inflammation or post-treatment with other intravitreal agents, have been reported
with the use of ranibizumab products. Discontinue treatment with CIMERLI® in patients who
develop these events. Patients should be instructed to report any change in vision without
delay

| ICD-10-CM | Description |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E11.3499 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E11.3511 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E11.3512 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E11.3513 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E11.3521 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E11.3522 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E11.3523 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |
| E11.3529 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E11.3531 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E11.3532 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |
| E11.3533 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E11.3539 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |
| E11.3541 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E11.3542 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |
| E11.3543 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E11.3549 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E11.3551 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye |
| E11.3552 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye |

ADVERSE REACTIONS

 Serious adverse reactions related to the injection procedure that occurred in <0.1% of intravitreal injections, including endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract

| ICD-10-CM | Description |
|-----------|--------------------------------------------------------------------------------------------------------------------------|
| E11.3553 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral |
| E11.3559 | Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |
| E11.3591 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye |
| E11.3592 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye |
| E11.3593 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral |
| E11.3599 | Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |
| E13.311 | Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema |
| E13.319 | Other specified diabetes mellitus with unspecified diabetic retinopathy without macular edema |
| E13.3211 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3212 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye |
| E13.3213 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral |
| E13.3219 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3291 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye |
| E13.3292 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye |
| E13.3293 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral |
| E13.3299 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E13.3311 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3312 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye |
| E13.3313 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral |

ADVERSE REACTIONS (continued)

 The most frequently reported ocular adverse reactions in ranibizumab-treated patients compared with the control group were conjunctival hemorrhage, eye pain, vitreous floaters, and increased intraocular pressure. The most common non-ocular adverse reactions were nasopharyngitis, anemia, nausea, and cough

| ICD-10-CM | Description |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------|
| E13.3319 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3391 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye |
| E13.3392 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye |
| E13.3393 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral |
| E13.3399 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E13.3411 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye |
| E13.3412 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye |
| E13.3413 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral |
| E13.3419 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3491 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye |
| E13.3492 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye |
| E13.3493 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral |
| E13.3499 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye |
| E13.3511 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye |
| E13.3512 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye |
| E13.3513 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral |
| E13.3519 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3521 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye |
| E13.3522 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye |
| E13.3523 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral |

ADVERSE REACTIONS (continued)

 As with all therapeutic proteins, there is the potential for an immune response in patients treated with ranibizumab products. The clinical significance of immunoreactivity to ranibizumab products is unclear at this time.

| ICD-10-CM | Description |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E13.3529 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye |
| E13.3531 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye |
| E13.3532 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye |
| E13.3533 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral |
| E13.3539 | Other specified diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye |
| E13.3541 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye |
| E13.3542 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye |
| E13.3543 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral |
| E13.3549 | Other specified diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye |
| E13.3551 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, right eye |
| E13.3552 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, left eye |
| E13.3553 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, bilateral |
| E13.3559 | Other specified diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye |
| E13.3591 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye |
| E13.3592 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye |
| E13.3593 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral |
| E13.3599 | Other specified diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye |

Postmarketing Experience

The following adverse reaction has been identified during post-approval use of ranibizumab products:

Ocular: Tear of retinal pigment epithelium among patients with neovascular AMD

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz, Inc at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



MYOPIC CHOROIDAL NEOVASCULARIZATION (MCNV)

For additional information:



Visit CIMERLI.com



Call 1-844-4SANDOZ (1-844-472-6369)



Contact your CIMERLI Sales Representative or Field Reimbursement Manager

Diagnosis Codes (ICD-10-CM codes) will vary based on clinical diagnosis and payer requirements. The following tables list diagnosis codes that align with the FDA-approved indications for CIMERLI® but may not be all-inclusive. Clinical judgement should be used to determine the most appropriate codes. Please confirm coding requirements with each payer for each patient prior to drug administration.

The coding information contained herein is for informational purposes only and is not a guarantee of coverage or reimbursement for any product or service.

CONTRAINDICATIONS

 CIMERLI® (ranibizumab-eqrn) is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in CIMERLI®. Hypersensitivity reactions may manifest as severe intraocular inflammation.

MYOPIC CHOROIDAL NEOVASCULARIZATION (MCNV)

| ICD-10-CM | Description |
|-----------|----------------------------------------------------------------------|
| H44.2A1 | Degenerative myopia with choroidal neovascularization, right eye |
| H44.2A2 | Degenerative myopia with choroidal neovascularization, left eye |
| H44.2A3 | Degenerative myopia with choroidal neovascularization, bilateral eye |

WARNINGS AND PRECAUTIONS

• Endophthalmitis and Retinal Detachments: Intravitreal injections, including those with ranibizumab products, have been associated with endophthalmitis, retinal detachment, and iatrogenic traumatic cataract. Proper aseptic injection technique should always be utilized when administering CIMERLI®. In addition, patients should be monitored following the injection to permit early treatment, should an infection occur



Before prescribing, please see CIMERLI® <u>Prescribing Information</u>.

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