Ranibizumab

ACG: A-0450 (AC)
Link to Codes

MCG Health
Ambulatory Care
27th Edition

Clinical Indications

- Ranibizumab may be indicated when **ALL** of the following are present(1)(2):
  - Age 18 years or older
  - Eye condition appropriate for ranibizumab treatment, as indicated by **1 or more** of the following:
    - Diabetic macular edema[A](22)(23)(24)(25)(26)(27)N
    - Diabetic retinopathy[B](24)(25)(36)(44)N
    - Macular edema following retinal vein occlusion[C](48)(49)(50)(51)(52)N
    - Myopic choroidal neovascularization[D](63)N
    - Neovascular (wet, or exudative) age-related macular degeneration[E](23)(70)(71)(72)(73)(74)(75)N
    - Polypoid choroidal vasculopathy[F] with active juxtafoveal or subfoveal lesions and **ALL** of the following(90):N
      - Diagnosis of polypoid choroidal vasculopathy and **1 or more** of the following:
        - Fluorescein angiography results show leakage at retinal pigment epithelium.
        - Pigment epithelium detachment
        - Subretinal or intraretinal fluid
        - Subretinal hemorrhage or sub-retinal pigment epithelium hemorrhage
        - Vision loss attributable to polypoid choroidal vasculopathy
      - Concurrent administration with verteporfin photodynamic therapy
  - No concurrent ocular or periocular infection

Evidence Summary

Background

Ranibizumab is a recombinant human monoclonal antibody that acts as an antagonist to vascular endothelial growth factor and inhibits angiogenesis and vascular permeability.(1)(3) **(EG 2)**

Criteria

For diabetic macular edema, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Meta-analyses and systematic reviews demonstrated that all vascular endothelial growth factor inhibitors appear to have some activity against diabetic macular edema,(28) with some clinical trial evidence suggesting that aflibercept may improve best-corrected visual acuity (measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters) significantly compared with bevacizumab, without a statistically significant difference compared with ranibizumab.(29) **(EG 1)** A randomized study of 854 eyes in 691 patients with diabetic macular edema assigned patients to sham injection with prompt laser, ranibizumab injection with prompt laser, triamcinolone injection with prompt laser, or ranibizumab injection with laser deferred by at least 24 weeks. After 1 year of follow-up, ranibizumab with prompt or deferred laser appeared to be the most effective treatment.(30) **(EG 1)** Longer-term 3-year and 5-year follow-up studies of patients enrolled in this trial reported that continued ranibizumab therapy resulted in improved foveal thickness and best-corrected visual acuity, and that adding prompt laser is no better, and possibly worse, than deferring laser treatment for at least 24 weeks. However, the number of cumulative ranibizumab injections was fewer in the prompt laser group, which may have been responsible for some of the observed differences.(31)(32) **(EG 1)** A randomized controlled trial of 396 patients showed that ranibizumab monotherapy or ranibizumab combined with laser showed superior improvements in best-corrected visual acuity as compared with laser treatment alone.(33) **(EG 1)** Systematic and literature reviews of randomized controlled trials concluded that in a proportion of patients with diabetic macular edema, vascular endothelial growth factor inhibitors such as ranibizumab result in better visual acuity than treatment with laser photocoagulation or sham therapy. However, the authors acknowledged that long-term efficacy and the number of

ranibizumab injections required for long-term improvement of diabetic macular edema are unknown.(34)(35) **(EG 1)** Two parallel, phase III, multicenter, double-blind, sham injection-controlled, randomized studies of 377 and 382 patients with decreased vision due to diabetic macular edema studied the effect of monthly intravitreal injections of ranibizumab on best-corrected visual acuity at 24 months. Results showed that patients treated with monthly injections of 0.3 mg of ranibizumab were more likely to gain 15 or more letters on an eye chart, as compared with sham patients (34% to 45% vs 12% to 18%, respectively). In addition, improvement in macular edema was seen on optical coherence tomography.(36) **(EG 1)** A study of 759 patients from both trials reported that intravitreal ranibizumab significantly reduced the risk of progression of diabetic macular edema as compared with sham treatment at 3-year follow-up.(37) **(EG 1)** A randomized study focusing specifically on patient-reported visual outcomes in diabetic macular edema confirmed significant incremental benefit from ranibizumab, with reported subjective improvement reflecting objectively documented visual acuity improvement.(38) **(EG 1)** A randomized study of 660 adults with diabetic macular edema who received either intravitreal aflibercept, ranibizumab, or bevacizumab found that, after 1 year, visual acuity improvement was comparable among all 3 drugs in those with mild initial visual acuity loss.(39) **(EG 1)** A follow-up study found that all 3 groups showed continuing improvement in visual acuity for up to 2 years, with similar improvement across all 3 drugs in eyes with better baseline acuity.(40)(41) **(EG 1)** A secondary analysis also found, at 2-year follow-up, that aflibercept, bevacizumab, and ranibizumab therapy for diabetic macular edema resulted in an improvement in diabetic retinopathy in 24.8%, 22.1%, and 31.0%, respectively, of eyes with nonproliferative diabetic retinopathy at baseline and 70.4%, 30.3%, and 37.5%, respectively, of eyes with proliferative diabetic retinopathy at baseline.(41) **(EG 1)** Randomized studies of patients with diabetic macular edema who received ranibizumab for 12 to 36 months have shown that diabetic retinopathy often improves or worsens to a lesser degree.(42) **(EG 1)** A systematic review and meta-analysis of 8 randomized controlled trials (817 eyes) evaluating the efficacy of intravitreal ranibizumab or bevacizumab combined with intravitreal steroids for the treatment of diabetic macular edema found no difference in both the mean change in visual acuity and central macular thickness at 6-month to 2-year follow-up compared with vascular endothelial growth factor inhibitor therapy alone. Additionally, combination therapy was associated with an increased rate of cataract development and raised intraocular pressure.(43) **(EG 1)**

For diabetic retinopathy, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Two parallel, phase III, multicenter, double-blind, sham injection-controlled, randomized studies of 377 and 382 patients studied the effect of monthly intravitreal injections of ranibizumab on impaired vision due to diabetic macular edema. At 24 months, patients given ranibizumab as compared with sham treatment noted improved visual acuity and were less likely to develop proliferative diabetic retinopathy (3.6% vs 13.2%, respectively).(36) **(EG 1)** A randomized controlled study with 305 adults and 394 eyes with diabetic proliferative retinopathy assigned patients to treatment with either intravitreal ranibizumab or panretinal photocoagulation; 108 eyes (53%) treated with panretinal photocoagulation also received ranibizumab for diabetic macular edema, either at baseline or during the 2-year trial. At 2-year follow-up, 47% of eyes treated with ranibizumab improved 2 steps or greater in diabetic retinopathy severity as measured by fundus photography; additionally, visual acuity in patients given ranibizumab was noninferior to those treated with panretinal photocoagulation.(44) **(EG 1)** An extension of this study found, at 5-year follow-up, that visual acuity letter scores and mean visual acuity were similar between the ranibizumab and photocoagulation treatment groups. However, treatment with ranibizumab was associated with fewer patients developing vision-impairing diabetic macular edema compared with photocoagulation.(45) **(EG 1)** A phase II study of 106 patients with proliferative diabetic retinopathy compared treatment with ranibizumab, panretinal laser photocoagulation, or the combination of both and found, at 12-month follow-up, that ranibizumab monotherapy was associated with a decrease from baseline in the area of neovascularization and improved best-corrected visual acuity compared with laser photocoagulation monotherapy; no difference was seen between either monotherapy compared with combination therapy.(46) **(EG 1)**

For macular edema following retinal vein occlusion, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Meta-analyses and systematic reviews have confirmed efficacy and safety of vascular endothelial growth factor inhibitors for treatment of central and branch retinal vein occlusion for up to 26 to 52 weeks.(53)(54)(55)(56) **(EG 1)** A network meta-analysis of 8 randomized controlled studies of various interventions for branch retinal vein occlusion found no statistically significant difference between aflibercept and ranibizumab in terms of efficacy.(57) **(EG 1)** A systematic review and meta-analysis of 5 studies including 678 patients with macular edema due to branch retinal vein occlusion compared treatment with ranibizumab or dexamethasone intravitreal implant and found, at 6-month follow-up, that ranibizumab was associated with improved best-corrected visual acuity from baseline compared with dexamethasone.(58) **(EG 1)** A randomized controlled trial of 98 patients with either central or branch retinal vein occlusion found that intravitreal bevacizumab and ranibizumab have similar efficacy in improving both macular thickness and visual acuity after 6 months.(59) **(EG 1)** A randomized noninferiority trial of 463 patients with macular edema due to central retinal vein occlusion compared treatment with ranibizumab, aflibercept, or bevacizumab and found, at 100 weeks' follow-up, mean gains in best-corrected visual acuity letter scores of 12.5, 15.1, and 9.8 in patients treated with ranibizumab, aflibercept, and bevacizumab, respectively. The authors found that aflibercept was noninferior compared with ranibizumab; however, bevacizumab was not noninferior compared with ranibizumab.(60) **(EG 1)** Specialty society guidelines state that several studies support ranibizumab for treatment of macular edema due to retinal vein occlusion.(61)(62) **(EG 2)**

For myopic choroidal neovascularization, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A meta-analysis and systematic review of 6 randomized studies of 594 patients with myopic choroidal neovascularization found low-certainty to moderate-certainty evidence that ranibizumab is effective in treating this condition for up to a period of 1 to 2 years.(64) **(EG 1)** A technology assessment and systematic reviews of randomized controlled trials report that ranibizumab may be an effective option for myopic choroidal neovascularization, although there is uncertainty about longer-term effectiveness.(65)(66)(67) **(EG 1)** A specialty society consensus statement supported by a literature review recommends that vascular endothelial growth factor inhibitor therapy should be the first-line treatment for patients with myopic choroidal neovascularization.(68) **(EG 2)**

For neovascular age-related macular degeneration, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A meta-analysis of 15 randomized controlled trials (8320 patients) evaluating the relative efficacy of vascular endothelial growth factor inhibitors for neovascular age-related macular degeneration found that ranibizumab and bevacizumab had comparable best-corrected visual acuity at 1 and 2 years of treatment, while ranibizumab had a greater reduction in central macular thickness from baseline at 2-year follow-up.(75) **(EG 1)** A systematic review and meta-analysis of randomized controlled trials reported that ranibizumab is effective in improving visual acuity.(76) **(EG 1)** A meta-analysis and systematic review identified 2 randomized trials with a total of 2457 patients with neovascular age-related macular degeneration who received either intravitreal aflibercept or ranibizumab and found that patients achieved comparable improvement in visual acuity with either drug up to 1 year after initiation of treatment.(77) **(EG 1)** However, other authors have found that intraocular pressure is higher in patients who receive ranibizumab as compared with aflibercept.(78) **(EG 1)** A randomized trial of 278 patients with neovascular age-related macular degeneration compared treatment with intravitreal ranibizumab or aflibercept and found, at 24-month follow-up, no difference in development or growth of macular atrophy or change in best-corrected visual acuity between the groups.(79) **(EG 1)** In a multicenter randomized single-blind trial, 1208 patients with neovascular age-related macular degeneration were assigned to receive intravitreal injections of either bevacizumab or ranibizumab, either monthly or as needed with monthly evaluation. After 1 year, bevacizumab and ranibizumab had equivalent effects on visual acuity when administered according to the same schedule.(80) **(EG 1)** These results were maintained at 2-year follow-up.(81)(82)(83) **(EG 1)** Four randomized trials, of 610, 501, 441, and 327 patients with neovascular age-related macular edema, reported equivalent outcomes with either ranibizumab or bevacizumab at 1-year follow-up.(84)(85)(86)(87) **(EG 1)** A long-term open-label extension study of patients from 3 prior randomized clinical trials reported that patients with neovascular age-related macular edema receiving ranibizumab maintained vision for over 4 years.(88) **(EG 2)** A meta-analysis of randomized studies totaling 2686 patients receiving either bevacizumab or ranibizumab for neovascular age-related macular edema confirmed that both drugs had comparable positive effects on visual acuity after 1 year, but that bevacizumab was associated with a higher risk of serious systemic adverse events.(89) **(EG 1)** A specialty society guideline recommends ranibizumab as a management option for patients with age-related neovascular macular degeneration.(70) **(EG 2)**

For polypoid choroidal vasculopathy, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A randomized controlled trial of 322 patients with symptomatic macular polypoidal choroidal vasculopathy who underwent photodynamic therapy with verteporfin in combination with ranibizumab found, at 12-month follow-up, a greater improvement in best-corrected visual acuity from baseline (8.3 letters) and a higher rate of complete polyp regression (69.3%) compared with ranibizumab treatment alone (5.1 letters improvement in best-corrected visual acuity from baseline and 34.7% complete polyp regression).(91) **(EG 1)** At 24-month follow-up, the adjusted mean best-corrected visual acuity gains were 9.6 letters and 5.5 letters in the combination therapy and ranibizumab groups, respectively, and complete polypoidal regression was 56.6% and 26.7% in the combination therapy and ranibizumab groups, respectively.(92) **(EG 1)** A meta-analysis and systematic review found 2 randomized studies involving 68 patients and determined that photodynamic therapy was more effective than ranibizumab at improving central retinal thickness and polypoidal regression at 6 months; however, both therapies appeared to be comparable in significantly improving visual acuity for up to 24 months.(93) **(EG 1)** An evidence-based guideline recommends initial treatment of juxtafoveal and subfoveal polypoidal choroidal vasculopathy with photodynamic therapy with verteporfin, either alone or combined with antiangiogenic therapy with ranibizumab, as well as retreatment for incomplete regression of polyps.(90) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For central serous chorioretinopathy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A meta-analysis and systematic review of interventions for central serous chorioretinopathy found 4 low-quality studies that showed no incremental difference in visual acuity after 6 months of treatment with either ranibizumab or bevacizumab. The authors indicated that additional study is needed.(4) **(EG 1)**

For choroidal neovascularization due to angioid streaks, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A retrospective case series of 39 patients (52 eyes) with choroidal neovascularization secondary to angioid streaks treated as needed with ranibizumab (33 eyes), bevacizumab (13 eyes), or a combination (6 eyes) found, at a mean follow-up of 33.8 months, that treatment slowed the progression of choroidal neovascularization but did not prevent progressive visual loss. Further prospective randomized studies were recommended.(5) **(EG 2)** A phase I randomized controlled trial (30 patients) compared scheduled monthly intravitreal ranibizumab with 3 monthly injections followed by as-needed dosing in patients with choroidal neovascularization (including 3 with angioid streaks) and found, at 12-month follow-up, that visual acuity improved similarly in both groups. Due to the small number of patients, the authors recommended larger randomized studies to confirm the findings.(6) **(EG 1)**

For neovascular glaucoma, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A meta-analysis and systematic review studying the subconjunctival use of ranibizumab or bevacizumab to inhibit scar formation after trabeculectomy for glaucoma found 5 randomized controlled trials involving 177 eyes; however, the studies were heterogeneous and of low quality, and the authors stated that the evidence was insufficient to refute or support the use of ranibizumab or bevacizumab for this indication.(7) **(EG 1)** A systematic review evaluating intravitreal anti-vascular endothelial growth factors for treatment of neovascular glaucoma (including one study of ranibizumab) found inconsistent effects on post-treatment intraocular pressure and visual acuity; further studies were recommended.(8) **(EG 1)**

For ocular histoplasmosis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A retrospective chart review of 54 eyes with ocular histoplasmosis treated with

either intravitreal ranibizumab or bevacizumab found, at 26.8-month follow-up, that treatment was associated with improved visual acuity. Due to lack of direct comparison or control, further prospective randomized trials were recommended.(9) **(EG 2)** A randomized controlled trial (9 patients) compared intravitreal ranibizumab with intravenous verteporfin phototherapy for treatment of ocular histoplasmosis and found, at 1-year follow-up, no difference in visual acuity measures between groups; notably, all patients in the phototherapy group received rescue ranibizumab due to symptom worsening on phototherapy alone. The authors recommended further, larger randomized trials.(10) **(EG 1)** A phase I randomized controlled trial (30 patients) compared scheduled monthly intravitreal ranibizumab with 3 monthly injections followed by as-needed dosing in patients with choroidal neovascularization (including 9 with ocular histoplasmosis) and found, at 12-month follow-up, that visual acuity improved similarly in both groups. Due to the small number of patients, the authors recommended larger randomized studies to confirm the findings.(6) **(EG 1)**

For radiation retinopathy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** An industry-sponsored phase IIb randomized trial of 40 untreated patients with radiation-induced macular edema and decreased visual acuity (2.5 years after radiation therapy) compared 3 treatment regimens for 1 year (monthly ranibizumab alone, monthly ranibizumab plus targeted retinal photocoagulation, or as-needed ranibizumab plus targeted retinal photocoagulation after 3 monthly ranibizumab doses) followed by a treat-and-extend regimen for an additional year and found, at 48-week follow-up, improved central macular thickness and best-corrected visual acuity in all 3 arms; by 104-week follow-up, these improvements regressed to baseline and remained similar in all 3 arms. However, the authors noted that the small sample size and losses to follow-up limited the results, and further large randomized controlled trials were recommended.(11)(12) **(EG 1)** A retrospective review of 120 patients with radiation retinopathy treated with intravitreal ranibizumab or bevacizumab found, at a mean treatment interval of 38 months, that 80% of patients who received 3 or more injections remained within 2 lines of their initial visual acuity or better, with few acute or long-term side effects noted. However, due to the uncontrolled nature of the review, the authors noted that outcome assessments were limited.(13) **(EG 2)**

For retinal angiomatous proliferation, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A prospective case series of 31 patients treated over 13 months found that intravitreal ranibizumab resulted in improvements in both visual acuity and macular thickness. The authors concluded that longer-term randomized controlled studies are warranted.(14) **(EG 2)** Similar results were noted in a retrospective case series of 20 eyes in 15 patients, after up to 24 months, but the results for visual improvement were only statistically significant for the first 3 months.(15) **(EG 2)** A randomized study assigned 50 patients with early or moderate disease to either intravitreal bevacizumab or ranibizumab; each group demonstrated comparable significant improvement after 1 year. However, there was no untreated control group, and the authors indicated that large randomized studies are needed.(16) **(EG 1)**

For retinopathy of prematurity, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review included 5 randomized controlled trials (307 infants) evaluating the efficacy of intravitreal ranibizumab or bevacizumab in preterm infants with type 1 retinopathy of prematurity and found no decrease in the risks of retinal detachment, disease recurrence, and corneal or lens opacities requiring treatment compared with conventional laser therapy. The authors concluded that further studies are needed to evaluate structural and functional outcomes in childhood and delayed systemic effects.(17) **(EG 1)** A randomized open-label trial that included 225 infants born at less than 1500 grams with bilateral retinopathy of prematurity reported that intravitreal ranibizumab was not significantly more likely than laser therapy to lead to treatment success, as defined by survival without active retinopathy of prematurity, unfavorable structural outcomes, or treatment switch, at 24 weeks of follow-up at either of 2 doses. The study was limited by slow enrollment requiring a change in total patients per treatment arm and potential for bias due to individualized retreatment decisions and other factors.(18) **(EG 1)** A specialty society technology assessment found low-quality to moderate-quality evidence that vascular endothelial growth factor inhibitors are as effective as laser photocoagulation for achieving regression of acute type 1 retinopathy of prematurity; treatment with vascular endothelial growth factor inhibitors is associated with increased recurrence. The authors recommended further research to evaluate the long-term safety of these agents as well as the optimal choice of drug.(19) **(EG 2)**

For uveitis complications such as cytoid macular edema, choroidal neovascularization, and retinal neovascularization, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of vascular endothelial growth factor inhibitors found mainly small case series and concluded that prospective studies are needed to evaluate use for these conditions.(20) **(EG 2)**

For vitreous hemorrhage secondary to diabetic retinopathy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A multicenter, randomized, double-masked, controlled trial of 261 eyes in 261 patients with vitreous hemorrhage found no significant clinical difference between treatment with ranibizumab vs saline injection on the cumulative probability of subsequent vitrectomy at 16 weeks.(21) **(EG 1)**

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Footnotes

[A] For diabetic macular edema, ranibizumab is administered by intravitreal injection every 28 days, followed by careful monitoring for signs of increased ocular pressure or endophthalmitis.(1) [A in Context Link 1]

[B] For diabetic retinopathy, ranibizumab is administered by intravitreal injection every 28 days, followed by careful monitoring for signs of increased ocular pressure or endophthalmitis.(1) [B in Context Link 1]

[C] For macular edema following retinal vein occlusion, ranibizumab is administered by intravitreal injection every 28 days, followed by careful monitoring for signs of increased ocular pressure or endophthalmitis. In clinical studies for this indication, patients received monthly injections for 6 months.(1)(47) [C in Context Link 1]

[D] For myopic choroidal neovascularization, ranibizumab is administered by intravitreal injection every 28 days for a total of 3 doses, followed by careful monitoring for signs of increased ocular pressure or endophthalmitis.(1) [D in Context Link 1]

[E] For neovascular age-related macular degeneration, ranibizumab is administered by intravitreal injection every 28 days, followed by careful monitoring for signs of increased ocular pressure or endophthalmitis.(1) After 4 consecutive months of administration, the injection frequency may be reduced to every 3 months, if necessary, although the visual acuity benefit may be reduced in some patients.(69) [E in Context Link 1]

[F] Polypoid choroidal vasculopathy is characterized by polypoidal dilatations along a branching network of choroidal neovascularization, in which fragile blood vessels may leak or hemorrhage into the macula, resulting in vision loss and chorioretinal atrophy.(90) For active juxtafoveal or subfoveal polypoid choroidal vasculopathy, ranibizumab is administered by intravitreal injection monthly for 3 doses during verteporfin photodynamic therapy.(90) [F in Context Link 1]

Codes

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