PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	POLICY NUMBER	CRITERIA CHANGE	MATERIAL AMENDEMENT	EFFECTIVE DATE	LINK TO FULL POLICY
Certolizumab pegol (e.g., Cimzia)	2024037	Initial approval coverage criteria updated for Crohn's disease updated. CROHN'S DISEASE INITIAL APPROVAL: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor.	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024037

Guselkumab (e.g., Tremfya)	2024071	Criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> STANDARD REVIEW for up to 3 doses: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u>	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024071

		STANDARD REVIEW for up to 3 doses: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR b. Contraindication to conventional (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor.			
Mirikizumab-mrkz (e.g., Omvoh)	2024011	Criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> STANDARD REVIEW for up to 3 doses: 1. Individual is 18 years of age or older (Omvoh, 2025); AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024011

		greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u> STANDARD REVIEW for up to 3 doses: 1. Individual is 18 years of age or older (Omvoh, 2025); AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR			

		b. Contraindication to conventional (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor.			
Infliximab (e.g., Remicade and Unbranded Infliximab) and Biosimilars	1998161	Initial approval criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> INITIAL APPROVAL: 1. Individual is 6 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine,	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=1998161

		mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u> INITIAL APPROVAL: 1. Individual is 6 years of age or older; AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR b. Contraindication to conventional therapy (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including			

		but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor. Initial approval and authorization renewal criteria added for off-label immune-mediated toxicities (colitis, pneumonitis, enterocolitis, others). <u>Off-label Indications:</u> <u>IMMUNE-MEDIATED TOXICITIES (COLITIS, PNEUMONITIS, ENTEROCOLITIS, OTHERS)</u> INITIAL APPROVAL: 1. Individual is currently receiving or has recently received an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, ipilimumab, relatlimab, atezolizumab, durvalumab, cemiplimab) or other medication associated with immune-mediated toxicity (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 2. Individual has grade 2 to 4 or otherwise severe/ life-threatening toxicity (NCCN Management of Immunotherapy-Related Toxicities; Brahmer 2021); AND 3. Alternative etiologies, including infectious causes (e.g., Clostridioides difficile, bacterial, viral, or parasitic infection), have been reasonably excluded (NCCN Management of Immunotherapy-Related Toxicities; SITC Clinical Practice Guideline for Immunotherapy-Related Adverse Events); AND 4. Individual has received a high-dose systemic corticosteroid therapy (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 5. One of the following is present (NCCN Management of Immunotherapy-Related Toxicities; Dougan 2021):			

		a. No clinically meaningful improvement after at least 48 to 72 hours of corticosteroid therapy; OR b. Recurrence of symptoms during corticosteroid tapering; OR c. Contraindication, intolerance, or inability to receive corticosteroid therapy; AND 6. Recommendation for treatment with a biologic is made by an appropriate specialist (e.g., oncology, gastroenterology, pulmonology, rheumatology, nephrology) and clinical documentation is supporting use as medically appropriate option; AND 7. Individual is not using the medication in combination with any other biologic intended to treat immune-mediated toxicities, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus Kinase Inhibitor. AUTHORIZATION RENEWAL: 1. Condition improved with treatment as documented by positive clinical response; AND 2. Manageable or no side effects; AND 3. Continuation may be considered for up to two additional doses when documentation demonstrates persistent or recurrent symptoms requiring ongoing treatment.			
Natalizumab (e.g., Tysabri) and Biosimilars	2016018	Initial approval criteria updated for Crohn's disease. <u>CROHN'S DISEASE</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older (Tysabri, 2025); AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016018

		least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor.			
Risankizumab (e.g., Skyrizi)	2022031	Initial approval criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide,	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022031

		hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR b. Contraindication to conventional therapy (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR			

		d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor.			
Tocilizumab (e.g., Actemra) and Biosimilars	2020022	Initial approval and authorization renewal criteria added for off-label immune-mediated toxicities (colitis, pneumonitis, enterocolitis, others). <u>Off-label Indications:</u> <u>IMMUNE-MEDIATED TOXICITIES (COLITIS, PNEUMONITIS, ENTEROCOLITIS, OTHERS)</u> INITIAL APPROVAL: 1. Individual is currently receiving or has recently received an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, ipilimumab, relatlimab, atezolizumab, durvalumab, cemiplimab) or other medication associated with immune-mediated toxicity (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 2. Individual has grade 2 to 4 or otherwise severe/ life-threatening toxicity (NCCN Management of Immunotherapy-Related Toxicities; Brahmer 2021); AND 3. Alternative etiologies, including infectious causes (e.g., Clostridioides difficile, bacterial, viral, or parasitic infection), have been reasonably excluded (NCCN Management of Immunotherapy-Related Toxicities; SITC Clinical Practice Guideline	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020022

		for Immunotherapy-Related Adverse Events); AND 4. Individual has received a high-dose systemic corticosteroid therapy (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 5. One of the following is present (NCCN Management of Immunotherapy-Related Toxicities; Dougan 2021): a. No clinically meaningful improvement after at least 48 to 72 hours of corticosteroid therapy; OR b. Recurrence of symptoms during corticosteroid tapering; OR c. Contraindication, intolerance, or inability to receive corticosteroid therapy; AND 6. Recommendation for treatment with a biologic is made by an appropriate specialist (e.g., oncology, gastroenterology, pulmonology, rheumatology, nephrology) and clinical documentation is supporting use as medically appropriate option; AND 7. Individual is not using the medication in combination with any other biologic intended to treat immune-mediated toxicities, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus Kinase Inhibitor. AUTHORIZATION RENEWAL: 1. Condition improved with treatment as documented by positive clinical response; AND 2. Manageable or no side effects; AND 3. Continuation may be considered for up to two additional doses when documentation demonstrates persistent or recurrent symptoms requiring ongoing treatment.			

Ustekinumab (e.g., Stelara) and Biosimilars	2021028	Initial approval criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> INITIAL APPROVAL: 1. Individual is 2 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR 6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u> INITIAL APPROVAL:	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021028

		1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR b. Contraindication to conventional therapy (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor. Initial approval and authorization renewal criteria added for off-label immune-mediated toxicities (colitis, pneumonitis, enterocolitis, others). <u>Off-label Indications:</u> <u>IMMUNE-MEDIATED TOXICITIES (COLITIS, PNEUMONITIS, ENTEROCOLITIS, OTHERS)</u> INITIAL APPROVAL: 1. Individual is currently receiving or has recently received an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, ipilimumab, relatlimab, atezolizumab, durvalumab, cemiplimab) or other			

		medication associated with immune-mediated toxicity (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 2. Individual has grade 2 to 4 or otherwise severe/ life-threatening toxicity (NCCN Management of Immunotherapy-Related Toxicities; Brahmer 2021); AND 3. Alternative etiologies, including infectious causes (e.g., Clostridioides difficile, bacterial, viral, or parasitic infection), have been reasonably excluded (NCCN Management of Immunotherapy-Related Toxicities; SITC Clinical Practice Guideline for Immunotherapy-Related Adverse Events); AND 4. Individual has received a high-dose systemic corticosteroid therapy (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 5. One of the following is present (NCCN Management of Immunotherapy-Related Toxicities; Dougan 2021): d. No clinically meaningful improvement after at least 48 to 72 hours of corticosteroid therapy; OR e. Recurrence of symptoms during corticosteroid tapering; OR f. Contraindication, intolerance, or inability to receive corticosteroid therapy; AND 6. Recommendation for treatment with a biologic is made by an appropriate specialist (e.g., oncology, gastroenterology, pulmonology, rheumatology, nephrology) and clinical documentation is supporting use as medically appropriate option; AND 7. Individual is not using the medication in combination with any other biologic intended to treat immune-mediated toxicities, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus Kinase Inhibitor.			

		AUTHORIZATION RENEWAL: 1. Condition improved with treatment as documented by positive clinical response; AND 2. Manageable or no side effects; AND 3. Continuation may be considered for up to two additional doses when documentation demonstrates persistent or recurrent symptoms requiring ongoing treatment.			
Vedolizumab (e.g., Entyvio) for Inflammatory Bowel Disease	2015011	Initial approval criteria updated for Crohn's disease and ulcerative colitis. <u>CROHN'S DISEASE</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe Crohn's disease supported by the submitted medical records; AND 3. Individual has an active disease with documented inadequate response (trial of greater than or equal to 3 months) to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Lichtenstein, 2018); OR 4. Individual has an active disease with intolerance or contraindication to at least one conventional therapy option (e.g., betamethasone, methylprednisolone, prednisolone, prednisone, budesonide, hydrocortisone, azathioprine, mercaptopurine, sulfasalazine, mesalamine, methotrexate) (Van Rheenen, 2021); OR 5. Individual has previously received a biologic (e.g., adalimumab, infliximab, certolizumab pegol, risankizumab, ustekinumab, natalizumab, vedolizumab) or Janus Kinase Inhibitor (e.g., upadacitinib) indicated for moderate to severe Crohn's disease; OR	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=20150121

		6. Individual has disease with high-risk features (see policy guidelines, ACG, 2025); AND 7. Individual is not using the medication in combination with any other biologic, including but not limited to: TNF inhibitor, IL-36 inhibitor, integrin inhibitor, any other IL inhibitor, or Janus kinase inhibitor. <u>ULCERATIVE COLITIS</u> INITIAL APPROVAL: 1. Individual is 18 years of age or older; AND 2. Individual has a diagnosis of moderate to severe ulcerative colitis supported by the submitted medical records AND meets one of the following: a. Inadequate response, loss of response, or intolerance to at least one conventional therapy (ECCO 2022); OR b. Contraindication to conventional therapy (ECCO 2022); OR c. Previously received an FDA-approved biologic or targeted synthetic therapy for ulcerative colitis; OR d. Treating provider documents that advanced therapy is clinically appropriate due to disease severity, prognostic factors, or anticipated inadequate response to conventional therapy (ACG, 2025); AND 3. Individual is not using the medication in combination with any other biologic intended to treat ulcerative colitis, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus kinase inhibitor. Initial approval and authorization renewal criteria added for off-label immune-mediated toxicities (colitis, pneumonitis, enterocolitis, others).			

		Off-label Indications: IMMUNE-MEDIATED TOXICITIES (COLITIS, PNEUMONITIS, ENTEROCOLITIS, OTHERS) INITIAL APPROVAL: 1. Individual is currently receiving or has recently received an immune checkpoint inhibitor (e.g., pembrolizumab, nivolumab, ipilimumab, relatlimab, atezolizumab, durvalumab, cemiplimab) or other medication associated with immune-mediated toxicity (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 2. Individual has grade 2 to 4 or otherwise severe/ life-threatening toxicity (NCCN Management of Immunotherapy-Related Toxicities; Brahmer 2021); AND 3. Alternative etiologies, including infectious causes (e.g., Clostridioides difficile, bacterial, viral, or parasitic infection), have been reasonably excluded (NCCN Management of Immunotherapy-Related Toxicities; SITC Clinical Practice Guideline for Immunotherapy-Related Adverse Events); AND 4. Individual has received a high-dose systemic corticosteroid therapy (NCCN Management of Immunotherapy-Related Toxicities; ASCO Guideline Update for Management of Immune-Related Adverse Events); AND 5. One of the following is present (NCCN Management of Immunotherapy-Related Toxicities; Dougan 2021): a. No clinically meaningful improvement after at least 48 to 72 hours of corticosteroid therapy; OR b. Recurrence of symptoms during corticosteroid tapering; OR			

		c. Contraindication, intolerance, or inability to receive corticosteroid therapy; AND 6. Recommendation for treatment with a biologic is made by an appropriate specialist (e.g., oncology, gastroenterology, pulmonology, rheumatology, nephrology) and clinical documentation is supporting use as medically appropriate option; AND 7. Individual is not using the medication in combination with any other biologic intended to treat immune-mediated toxicities, including but not limited to: TNF inhibitor, IL-36 inhibitor, PDE4 inhibitor, any other IL inhibitor, or Janus Kinase Inhibitor. AUTHORIZATION RENEWAL: 1. Condition improved with treatment as documented by positive clinical response; AND 2. Manageable or no side effects; AND 3. Continuation may be considered for up to two additional doses when documentation demonstrates persistent or recurrent symptoms requiring ongoing treatment.			
Tisagenlecleucel (e.g., Kymriah)	2020001	Coverage criteria for all FDA labeled indications updated. Off-label indications updated. <u>FDA Labeled Indications:</u> <u>RELAPSED OR REFRACTORY B-CELL ACUTE LYMPHOBLASTIC LEUKEMIA</u> STANDARD REVIEW: 1. Individual has a histologically confirmed diagnosis of B-cell acute lymphoblastic leukemia with morphologic bone marrow tumor involvement (≥5% lymphoblasts) that is refractory or in second or later relapse (Kymriah, 2025); AND 2. Individual is 25 years of age or less at the time of infusion; AND	No	October 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020001

		3. Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist; AND 4. Individual has confirmed CD19 tumor expression (Kymriah, 2025); AND 5. Individual does not have ANY of the following: a. Active central nervous system (CNS) lymphoma; OR 6. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for CAR T-cell therapy or other genetically modified T-cell therapy; AND 7. There is only one administration of tisagenlecleucel per individual per lifetime. <u>RELAPSED OR REFRACTORY LARGE B-CELL LYMPHOMA</u> STANDARD REVIEW: 1. Individual is 18 years of age or older at the time of infusion; AND 2. Individual has a histologically confirmed diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B cell lymphoma and DLBCL arising from follicular lymphoma; AND 3. Individual has received adequate prior therapy including ALL the following: a. Anti-CD20 monoclonal antibody for CD20-positive tumor (e.g., rituximab); AND b. Anthracycline-containing chemotherapy regimen; AND c. For individuals with transformed follicular lymphoma, prior chemotherapy for follicular lymphoma and subsequently have chemo refractory disease after			

		transformation to diffuse large B-cell lymphoma; AND 4. Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist; AND 5. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for CAR T-cell therapy or other genetically modified T-cell therapy; AND 6. Individual does not have primary central nervous system lymphoma; AND 7. There is only one administration of tisagenlecleucel per individual per lifetime. <u>FOLLICULAR LYMPHOMA (FL)</u> STANDARD REVIEW: 1. Individual is 18 years of age or older at the time of infusion; AND 2. Individual has a histologically confirmed diagnosis of *relapsed or **refractory follicular lymphoma; AND 3. Individual has received at least two prior lines of therapy (Kymriah, 2025); AND 4. Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist; AND 5. Individual ****does not have primary central nervous system lymphoma; AND 6. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for CAR T-cell therapy or other genetically modified T-cell therapy; AND 7. There is only one administration of tisagenlecleucel per individual per lifetime. <u>Off-label Indications:</u> STANDARD REVIEW:			

		1. Individual has a histologically confirmed diagnosis of one of the following: a. Pediatric Acute Lymphoblastic Leukemia (NCCN 2A); OR b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Histologic Transformation (Richter) (NCCN 2A); OR c. HIV-related B cell Lymphomas (NCCN 2A); OR d. Histologic Transformation of Indolent Lymphomas to DLBCL (NCCN 2A); OR e. B-Cell Lymphomas - Classic Follicular Lymphoma (NCCN 2A); OR f. B-Cell Lymphomas - Diffuse Large B-Cell Lymphoma (NCCN 2A); OR g. B-Cell Lymphomas - High-Grade B-Cell Lymphomas (NCCN 2A); OR h. B-Cell Lymphomas - Post-Transplant Lymphoproliferative Disorders (NCCN 2A); OR i. Acute Lymphoblastic Leukemia (NCCN 2A); AND 2. Individual has adequate organ and bone marrow function as determined by the treating oncologist/hematologist; AND 3. Individual has not received prior treatment with CAR T-cell therapy or other genetically modified T-cell therapy and is not or has not been a subject of a clinical trial for any of the therapies listed in this policy; AND 4. There is only one administration of tisagenlecleucel per individual per lifetime.			
Immune Globulin, Primary and Secondary Immunodeficiencies	1997113	Policy transitioned to InterQual®.	Yes	November 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=1997113
Edaravone (e.g., Radicava)	2017026	Policy transitioned to InterQual®.	Yes	November 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2017026

Pegcetacoplan Intravitreal (e.g., Syfovre)	2023037	Policy transitioned to InterQual®.	Yes	November 28, 2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023037