Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date**: 5/**1/2019**
Policy Number: PA.CP.PHAR.260	**Effective Date: 01/2018** **Revision Date: 04/17/2019**
Policy Name: Rituximab (Rituxan)	**HC Approval Date:**

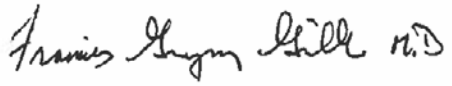
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2019 annual review: Rituxan biosimilar Truxima is added and applied to all policy criteria applicable to Rituxan; NHL criteria is edited to include all FDA approved or NCCN recommended NHL subtypes; additional NCCN recommended uses other than NHL are added section I.E. (NCCN compendium uses); hematologist added for all oncology indications; GPA/MPA dosing updated to delineate induction versus follow-up treatment and approval duration is edited from 4 weeks total to 6/12 months; PF off-label criteria is added; references reviewed and updated

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Rituximab (Rituxan)

Reference Number: PA.CP.PHAR.260
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

Description

Rituximab (Rituxan®) is a human monoclonal immunoglobulin G-1 (IgG1) kappa antibody directed against the CD20 antigen.

Rituximab-abbs (Truxima®) is a CD20-directed cytolytic antibody and biosimilar to Rituxan for the listed Truxima indications.

Rituximab and hyaluronidase (Rituxan Hycela™) is a combination of rituximab and human hyaluronidase that is used to increase the dispersion and absorption of the co-administered drugs when given subcutaneously.

FDA Approved Indication(s)

Indications		Rituxan	Truxima	Rituxan Hycela*
Oncology indications (adults)				
Low-grade and follicular B-cell NHL	Relapsed or refractory, low-grade *[Rituxan, Truxima]* or follicular *[Rituxan, Truxima, Rituxan Hycela]*, CD20-positive, B-cell NHL as a single agent	X	X	X
	Previously untreated follicular, CD20-positive B-cell NHL in combination with first-line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy	X	X	X
	Non-progressing (including stable disease), low-grade *[Rituxan, Truxima]* or follicular *[Rituxan Hycela]*, CD20-positive B-cell NHL as a single agent after first-line CVP chemotherapy	X	X	X
DLBCL *(a B-cell NHL)*	Previously untreated CD20-positive DLBCL in combination with CHOP or other anthracycline-based chemotherapy regimens	X		X
CLL *(a B-cell NHL)*	Previously untreated and treated CD20-positive CLL in combination with FC chemotherapy	X		X
Non-oncology indications (adults)				
RA	Moderately to severely active RA in combination with MTX in patients who have	X		

Indications		Rituxan	Truxima	Rituxan Hycela*
	inadequate response to one or more TNF antagonist therapies			
GPA, MPA	GPA and MPA in combination with glucocorticoids	X		
PV	Moderate to severe PV	X		

Abbreviations: CLL (chronic lymphocytic leukemia), DLBCL (diffuse large B-cell lymphoma), GPA (granulomatosis with polyangiitis; Wegener`s granulomatosis), MPA (microscopic polyangiitis), NHL (Non-Hodgkin's lymphoma), PV (pemphigus vulgaris), RA (rheumatoid arthritis).
**Rituxan Hycela limitations of use: 1) Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion; 2) Rituxan Hycela is not indicated for the treatment of non-malignant conditions.*

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Rituxan is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Hodgkin's Lymphoma *(includes chronic lymphocytic leukemia)* (must meet all):
1. Diagnosis of non-Hodgkin's lymphoma (NHL) or any of its subtypes
2. Age ≥ 18 years;
3. If request is for Rituxan Hycela, member has received at least one full dose of Rituxan;
4. Request meets any of the following (a or b):
   a. Dose does not exceed (i or ii):
      i. Rituxan: 500 mg/m^2 per IV infusion;
      ii. Rituxan Hycela: 1,600 mg/26,800 units SC;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Rheumatoid Arthritis (must meet all):
1. Diagnosis of rheumatoid arthritis (RA) ;
2. Request is for Rituxan/Truxima;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
   a. Failure of methotrexate (MTX) for ≥ 3 consecutive months at up to maximally indicated does, unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;

6. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
7. Rituxan/Truxima will be administered in combination with MTX unless contraindicated;
8. Prescribed dose does not exceed two-1000 mg infusions separated by 2 weeks followed by two-1000 mg IV infusions every 16 weeks.

Approval duration: 6 months

C. Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis (must meet all):

1. Diagnosis of GPA or MPA;
2. Request is for Rituxan/Truxima;
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Rituxan/Truxima will be administered in combination with glucocorticoid therapy;
6. Dose does not exceed (a or b):
   a. Induction: 375 mg/m^2 weekly for 4 weeks;
   b. Follow up treatment: two-500 mg infusions separated by 2 weeks, then 500 mg every 6 months.

Approval duration: 6 months

D. Pemphigus Vulgaris and Pemphigus Foliaceus (must meet all)**:**

1. Diagnosis of PV or pemphigus foliaceus (PF);
2. Request is for Rituxan/Truxima;
3. Prescribed by or in consultation with a dermatologist;
4. Age ≥ 18 years;
5. Dose does not exceed (a or b):
   a. Initial: two-1,000 mg infusions separated by 2 weeks;
   b. Maintenance: 500 mg every 6 months (starting 12 months after initial dose).

Approval duration: 6 months

E. NCCN **Compendium Indications (off-label)** (must meet all):

1. Diagnosis of any of the following:
   a. Primary CNS lymphoma;
   b. Leptomeningeal metastases;
   c. Nodular lymphocyte-predominant Hodgkin lymphoma;
   d. Acute lymphoblastic leukemia;
   e. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma;
   f. Immune checkpoint inhibitor-related toxicities;
2. Request is for Rituxan/Truxima;

3. Prescribed by or in consultation with an oncologist;
4. For nodular lymphocyte-predominant Hodgkin Lymphoma, age ≥ 18;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

F. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   b. Documentation supports that member is currently receiving Rituxan, Truxima, or Rituxan Hycela for a covered oncology indication;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets any of the following (a or b):
   a. New dose does not exceed the following:
      i. NHL:
         1. Rituxan/Truxima: 500 mg/m^2 per IV infusion;
         2. Rituxan Hycela: 1,600 mg/26,800 units per SC injection;
      ii. RA (Rituxan/Truxima): two-1,000 mg IV infusions every 16 weeks;
      iii. GPA/MPA (Rituxan/Truxima):
         a) Induction: 375 mg/m^2 IV weekly for up to 4 weeks total;
         b) Follow-up treatment: two-500 mg IV infusions separated by two weeks, then 500 mg IV every 6 months;
      iv. PV or PF (Rituxan/Truxima) (a or b):
         a) Maintenance: 500 mg IV every 6 months (starting 12 months after initial dose);
         b) Relapse: 1,000 mg IV once then 500 mg IV 16 weeks later, then 500 mg IV every 6 months;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CHOP: cyclophosphamide, doxorubicin, vincristine, prednisone
CLL: chronic lymphocytic leukemia
CVP: cyclophosphamide, vincristine, prednisone
DLBCL: diffuse large B-cell lymphoma
DMARD: disease-modifying antirheumatic drug
FC: fludarabine and cyclophosphamide
FDA: Food and Drug Administration
FL: follicular lymphoma
GPA: granulomatosis with polyangiitis (Wegener's granulomatosis)
MALT: mucosa-associated lymphoid tissue
MPA: microscopic polyangiitis
MTX: methotrexate
NHL: Non-Hodgkin's lymphoma
PF: pemphigus foliaceus
PV: pemphigus vulgaris
RA: rheumatoid arthritis
SLL: small lymphocytic lymphoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
RA		
azathioprine (Azasan®, Imuran®)	1 mg/kg/day PO QD or divided BID	2.5 mg/kg/day
Cuprimine® (d-penicillamine) *Off-label*	Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®) *Off-label*	Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	5 mg/kg/day
leflunomide (Arava®)	100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
methotrexate (Rheumatrex®)	7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
Ridaura® (auranofin)	6 mg PO QD or 3 mg PO BID	9 mg/day
sulfasalazine (Azulfidine®)	2 g/day PO in divided doses	3 gm/day
Enbrel (etanercept)	25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira (adalimumab)	40 mg SC every other week (may increase to once weekly)	40 mg/week
GPA, MPA		
glucocorticoids	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
  - Fatal infusion reactions (Rituxan, Truxima)
  - Severe mucocutaneous reactions, hepatitis B virus reactivation, progressive multifocal leukoencephalopathy (Rituxan, Truxima, Rituxan Hycela).

Appendix D: General Information

- Definition of MTX or Disease-Modifying Antirheumatic Drug (DMARD) failure
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to RA therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living

IV. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Rituxan, Truxima	Low-grade and follicular B-cell NHL	375 mg/m^2 IV infusion according to the following schedules: • Relapsed or refractory, low-grade or follicular, CD20+, B-cell NHL o Once weekly for 4 or 8 doses o Retreatment: once weekly for 4 doses • Previously untreated, follicular, CD20+, B-cell NHL: o Administer on Day 1 of each cycle of chemotherapy for up to 8 doses; o If complete or partial response, initiate Rituxan/Truxima maintenance treatment as a single-agent every 8 weeks for 12 doses to start 8 weeks following completion of a rituximab product in combination with chemotherapy. • Non-progressing, low-grade, CD20+, B-cell NHL, after first-line CVP chemotherapy: o Following completion of 6-8 cycles of CVP chemotherapy, administer once weekly for 4 doses at 6-month intervals to a maximum of 16 doses.	375 mg/m^2 IV infusion
Rituxan	Low-grade and follicular B-cell NHL	• Rituxan in combination with Zevalin for low-grade or follicular B-cell NHL: o 250 mg/m^2 IV within 4 hrs prior to administration of Indium-111-(In-111-) Zevalin and Yttrium-90-(Y-90) Zevalin. o Administer rituximab and In-111-Zevalin 7–9 days prior to rituximab and Y-90-Zevalin. o Refer to the Zevalin package insert for full prescribing information regarding the Zevalin therapeutic regimen.	375 mg/m^2 IV infusion

Drug Name	Indication	Dosing Regimen	Maximum Dose
Rituxan Hycela	Follicular B-cell NHL	1,400 mg rituximab and 23,400 units hyaluronidase SC according to the following schedules: ***First dose must be with IV Rituxan/Truxima if indicated with an asterisk (*).*** • Relapsed or refractory FL: o Once weekly for 3 or 7 weeks (i.e., 4 or 8 weeks in total)* o Retreatment: once weekly for 3 weeks (i.e., 4 weeks in total)* • Previously untreated FL: o Administer on Day 1 of Cycles 2–8 of chemotherapy (every 21 days), for up to 7 cycles (i.e., up to 8 cycles in total)* o If complete/partial response, initiate Rituxan Hycela maintenance treatment as a single-agent every 8 weeks for 12 doses to start 8 weeks following completion of Rituxan Hycela in combination with chemotherapy • Non-progressing FL after first-line CVP chemotherapy: o Following completion of 6–8 cycles of CVP chemotherapy, administer once weekly for 3 weeks (i.e., 4 weeks in total) at 6 month intervals to a maximum of 16 doses*	1,400 mg/23,400 units SC per injection
Rituxan	DLBCL *(a B-cell NHL)*	375 mg/m^2 IV infusion on Day 1 of each cycle of chemotherapy for up to 8 doses total.	375 mg/m^2 IV infusion
Rituxan Hycela	DLBCL *(a B-cell NHL)*	***First dose must be with IV Rituxan*** • 1,400 mg rituximab and 23,400 units hyaluronidase SC on Day 1 of Cycles 2–8 of CHOP chemotherapy for up to 7 cycles (i.e., up to 6–8 cycles in total)	1,400 mg/23,400 units SC per injection
Rituxan	CLL *(a B-cell NHL)*	375 mg/m^2 IV infusion on the day prior to initiation of FC chemotherapy, then 500 mg/m^2 on Day 1 of cycles 2-6 (every 28 days).	500 mg/m^2 per day
Rituxan Hycela	CLL *(a B-cell NHL)*	***First dose must be with IV Rituxan*** • 1,600 mg/26,800 units on Day 1 of Cycles 2–6 (every 28 days) for a total of 5 cycles (i.e., 6 cycles in total)	1,600 mg/26,800 units SC per injection

Drug Name	Indication	Dosing Regimen	Maximum Dose
Rituxan	RA	Two 1000 mg IV infusions separated by 2 weeks (i.e., day 1 and day 15), followed by two-1000 mg IV infusions every 16 weeks. Rituxan is given in combination with MTX.	1000 mg per week
Rituxan	GPA/MPA	Induction: • 375 mg/m^2 IV once weekly for 4 weeks in combination with glucocorticoids Follow-up treatment if disease control with induction treatment: • Two 500 mg IV infusions separated by 2 weeks, followed by 500 mg IV every 6 months thereafter based on clinical evaluation. Follow up treatment should be initiated: o Within 24 weeks after the last Rituxan induction infusion or based on clinical evaluation, but no sooner than 16 weeks after the last Rituxan induction infusion. o Within the 4 week period following achievement of disease control if induction was achieved with other immunosuppressants.	Induction: 375 mg/m^2 per week Follow-up treatment: 500 mg/dose (see regimen for dosing frequency)
Rituxan	PV	Initial and maintenance therapy: • Two 1,000 mg IV infusions separated by 2 weeks with a tapering course of glucocorticoids, then 500 mg IV at month 12 and every 6 months thereafter or based on clinical evaluation Relapse: • 1,000 mg IV once. Subsequent infusions may be administered no sooner than 16 weeks following the previous infusion.	Initial/relapse: 1000 mg/dose Maintenance: 500 mg/6 months

V. Product Availability

Drug Name	Availability
Rituximab (Rituxan)	Single-dose vials for IV injection: 100 mg/10 mL, 500 mg/50 mL
Rituximab-abbs (Truxima)	Single-dose vials for IV injection: 100 mg/10 mL, 500 mg/50 mL
Rituximab-hyaluronidase (Rituxan Hycela)	Single-dose vials for SC injection: 1,400 mg/23,400 units, 1,600 mg/26,800 units

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9310	Injection, rituximab, 100 mg

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
C79.32	Secondary malignant neoplasm of cerebral meninges
C81.00-C81.99	Hodgkin lymphoma
C82.00-C82.99	Follicular lymphoma
C83.00-C83.99	Non-follicular lymphoma
C84.60-C84.99	Mature T/NK –cell lymphomas
C85.10-C85.89	Other specified and unspecified types of non-Hodgkin lymphoma
C86.0-C86.5	Other specified types of T/NK-cell lymphoma
C88.0	Waldenstrom macroglobulinemia
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)
C91.00-C91.02	Acute lymphoblastic leukemia (ALL)
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type
C91.40-C91.42	Hairy cell leukemia
M05.00-M06.9	Rheumatoid arthritis
M31.30, M31.31	Wegener's granulomatosis
M31.7	Microscopic polyangiitis
D36.0	Benign neoplasm of lymph nodes
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD) (code first complications of transplanted organs and tissue (T86.-)
D59.1	Other autoimmune hemolytic anemias
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
T86.09	Complications of bone marrow transplant
T86.11	Kidney transplant rejection
T86.19	Other complications of kidney transplant
T86.298	Other complications of heart transplant
T86.39	Unspecified complication of heart-lung transplant
T86.5	Complications of stem cell transplant
Z85.71	Personal history of Hodgkin lymphoma
Z85.72	Personal history of non-Hodgkin lymphomas
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: summarized NCCN and FDA approved uses for improved clarity for Non-Hodgkin's Lymphoma; added specialist involvement in care into one criteria set; removed diagnosis requirement for ACR criteria in RA; revised conventional DMARD requirement in RA to require at least one conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine); off-label criteria added for additional NCCN-recommended diagnoses; removed off-label criteria for autoimmune hemolytic anemia and immune thrombocytopenia, will instead defer to off-label policy; approval durations updated; references reviewed and updated.	02.27.18	
2Q 2019 annual review: Rituxan biosimilar Truxima is added and applied to all policy criteria applicable to Rituxan; NHL criteria is edited to include all FDA approved or NCCN recommended NHL subtypes; additional NCCN recommended uses other than NHL are added section I.E. (NCCN compendium uses); hematologist added for all oncology indications; GPA/MPA dosing updated to delineate induction versus follow-up treatment and approval duration is edited from 4 weeks total to 6/12 months; PF off-label criteria is added; references reviewed and updated	04.17.19	

References

1. Rituxan Prescribing Information. South San Francisco, CA: Genentech Inc.; January 2019. Available at: https://www.gene.com/download/pdf/rituxan_prescribing.pdf. Accessed February 26, 2019.
2. Truxima Prescribing Information. North Wales, PA: Teva Pharmaceuticals, Inc.; November 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761088s000lbl.pdf. Accessed February 26, 2019.
3. Rituxan Hycela Prescribing Information. South San Francisco, CA: Genentech Inc.; April 2018. Available at: www.rituxanhycela.com. Accessed February 26, 2019.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed December 13, 2018.
5. Clinical Pharmacology Web site. Available at: http://clinicalpharmacology-ip.com. Accessed December 13, 2018.
6. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 26, 2019.
7. National Comprehensive Cancer Network. B-Cell Lymphomas Version 2.2019. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed February 26, 2019.
8. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2019. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed February 26, 2019.
9. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and

biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5): 625-639.
10. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2016 Jan; 68(1):1-25. doi: 10.1002/acr.22783. Epub 2015 Nov 6.
11. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014; 73: 492-509.
12. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. Arthritis Care Res (Hoboken). 2012 May; 64(5): 640–647. doi:10.1002/acr.21649.
13. Buch MH, Smolen JS, Betteridge N, et al. Updated consensus statement on the use of rituximab in patients with rheumatoid arthritis, Annals of the Rheumatic Diseases. 2011; 70(6): 909-920.
14. Birgens H, Frederiksen H, Hasselbalch HC, et al. A phase III randomized trial comparing glucocorticoid monotherapy versus glucocorticoid and rituximab in patients with autoimmune haemolytic anaemia. Br J Haematol. 2013 Nov; 163(3): 393-9. doi: 10.1111/bjh.12541. Epub 2013 Aug 24.
15. Barcellini W, Zaja F, Zaninoni A, et al. Sustained response to low-dose rituximab in idiopathic autoimmune hemolytic anemia. Eur J Haematol. 2013 Dec; 91(6): 546-51. Epub 2013 Oct 3.
16. Barcellini W, Zaja F, Zaninoni A. Low-dose rituximab in adult patients with idiopathic autoimmune hemolytic anemia: clinical efficacy and biologic studies. Blood. 2012; 119(16):3691. Epub 2012 Jan 20.
17. Berentsen S, Randen U, Vågan AM, et al. High response rate and durable remissions following fludarabine and rituximab combination therapy for chronic cold agglutinin disease. Blood. 2010; 116(17): 3180. Epub 2010 Jul 15.
18. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. April 2011; 117(16): 4190-4207.
19. Kim SJ, Lee JW, Jung CW, et al. Weekly rituximab followed by monthly rituximab treatment for steroid-refractory chronic graft-versus-host disease: results from a prospective, multicenter, phase II study. Haematologica. 2010; 95(11):1935.
20. Cutler C, Miklos D, Kim HT, et al. Rituximab for steroid-refractory chronic graft-versus-host disease. Blood. 2006;108:756-762.
21. Wolff D, Schleuning M, von Harsdorf S, et al. Consensus conference on clinical practice in chronic GVHD: second-line treatment of chronic graft-versus-host disease. Biol Blood Marrow Transplant. 2011;17:1-17.
22. Filipovich, AH, Weisdorf D, Pavletic S., et al. National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease: I. Diagnosis and Staging Working Group Report. Biol Blood Marrow Transplant. 2005 Dec;11(12):945-56.
23. Joly P, Maho-Vaillant M, Prost-Squarcioni C, et.al. First-line rituximab combined with short-term prednisone versus prednisone alone for the treatment of pemphigus (Ritux 3): a prospective, multicenter, parallel-group, open-label randomized trial. Lancet. 2017; 389: 2031–40.