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Heterogeneity of Treatment Regimens and Related Health Resource Use in Managing Patients With wAIHA: A US Multi-Database Retrospective Observational Study

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Introduction

Warm autoimmune hemolytic anemia (wAIHA)

- In wAIHA, autoantibodies (typically immunoglobulin G [IgG]) target red blood cell (RBC) surface antigens, resulting in RBC destruction in the spleen and liver[1,2]

Treatments

- Oral corticosteroids (OCSs) remain the first-line therapy for wAIHA
  - While one-third of patients experience a durable remission, the remainder have a chronic, relapsing course of disease[2]
  - Rescue therapies (eg, blood transfusions, intravenous [IV] corticosteroids, intravenous immunoglobulin [IVIg], erythropoiesis-stimulating agents [ESAs], plasma exchange [PEX]) are often required throughout the wAIHA treatment journey[3]
- Rituximab is frequently cited as a second-line agent following a loss of response to OCSs or a relapse
  - Use in clinical practice is often based on published retrospective data and expert opinion[2,4,5]
  - Real-world data characterizing the utilization patterns and associated outcomes are needed to inform clinical practice

Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM)

- The OMOP CDM is an open, standardized data model that allows inclusion of multiple data sources, enabling efficient, reliable, and reproducible evidence generation[6]

1. Brodsky RA. *N Engl J Med*. 2019;381(7):647-654. 2. Cavallaro F, et al. *Expert Opin Biol Ther*. 2023;23(12):1227-1237. 3. Jäger U, et al. *Blood Rev*. 2020;41:100648. 4. Barcellini W, Fattizzo B. *Blood*. 2021;137(10):1283-1294. 5. Murakhovskaya I. *J Clin Med*. 2020;9(12):4034. 6. OMOP Common Data Model. OHDSI CDM Working Group. Accessed October 16, 2025. https://ohdsi.github.io/CommonDataModel/

Objectives

To describe treatment patterns in the inpatient and outpatient settings among patients with newly diagnosed wAIHA in the United States

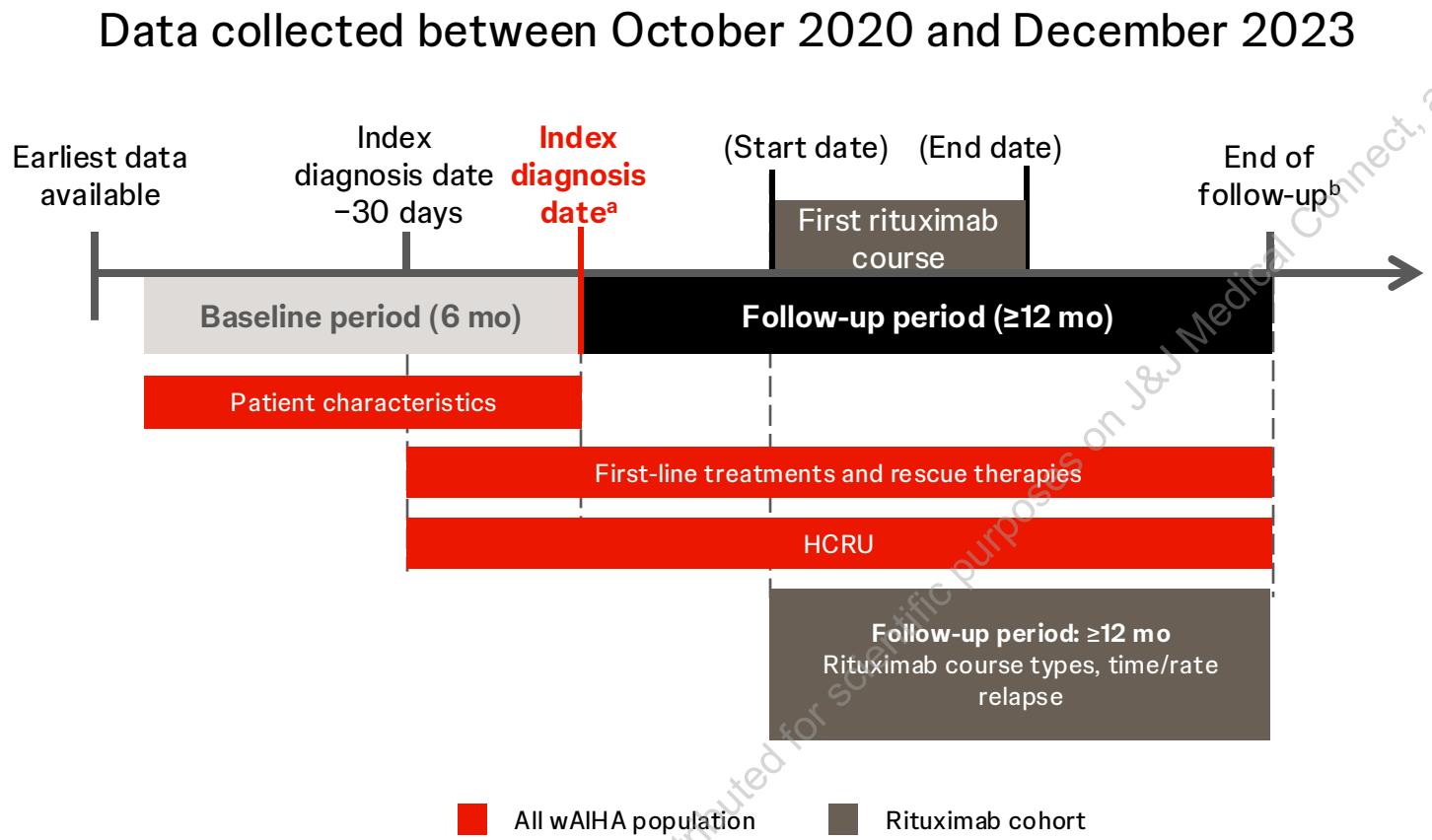
To characterize patterns of rituximab use in the United States during the first year after diagnosis of wAIHA

To evaluate the frequency and types of rescue therapy and healthcare resource utilization (HCRU) related to the current standard of care for wAIHA in the United States

Here, we present results from a retrospective US-based study using patient data from 6 insurance databases covering commercial, Medicare, and Medicaid beneficiaries

wAIHA=warm autoimmune hemolytic anemia.

Study Design and Cohorts



Overall population

- Patients ≥18 years of age with a wAIHA diagnosis[c] were included
  - Patients with a wAIHA diagnosis code after October 2020 were included; once identified, the patient's earliest AIHA diagnosis served as the wAIHA index diagnosis date[d]
  - wAIHA etiology was classified as primary or secondary[e]
  - Patients with a medical claim for cold or mixed AIHA were excluded

Rituximab cohort

- Included patients with records of ≥1 rituximab administration and ≥1 year of follow-up after the first infusion

[a]Continuous medical/pharmacy enrollment required 6 months prior to the index date and for ≥12 months post index. [b]Endpoints were assessed at 12 months from relevant start dates (eg, index diagnosis date minus 30, index diagnosis date, rituximab start date); follow-up data were collected beyond 12 months. [c]ICD-10-CM Diagnosis Code D59.11*. [d]ICD-10-CM code for wAIHA was first available in 2020 and may not have been adopted immediately, so the earliest AIHA diagnosis record among patients with a wAIHA code was used as a proxy. [e]Secondary wAIHA assumed with a history of hematologic malignancy, solid tumors, immunodeficiencies, or autoimmune disease in the 6 months prior to wAIHA diagnosis. **HCRU**=healthcare resource utilization, **ICD-10-CM**=*International Classification of Diseases, 10th Revision, Clinical Modification*, **wAIHA**=warm autoimmune hemolytic anemia.

Data Source, Endpoints, and Statistical Considerations

Data source

- The OMOP CDM was utilized to aggregate data from 6 databases
  - 5 claims databases: MarketScan® Commercial, Medicare, and Medicaid Databases; IQVIA PharMetrics; Optum Clinformatics®
  - 1 electronic health records (EHRs) database: Optum Pan-Therapeutic EHR

Endpoints

- Demographics and disease characteristics
- wAIHA-related treatments, including OCS, immunosuppressants, and rituximab (course types[a])
  - First-line therapy was defined as the first treatment occurring any time after 30 days prior to diagnosis
  - Combination therapy was defined as treatments started within 21 days of each other
- Rate and type of rescue therapy use within the 12 months of diagnosis (overall group) and before, during, and after rituximab (rituximab cohort)
- Overall and AIHA-related[b] HCRU within the first 12 months of wAIHA diagnosis

Statistical considerations

- This was a retrospective observational study; no formal statistical comparisons were made

[a]Rituximab regimens classified as 4-infusion regimen, 2-infusion regimen, single dose, or extended (>4 infusions).
[b]Related to ICD-10-CM Diagnosis Code D59.1*. **CDM**=Common Data Model, **HCRU**=healthcare resource utilization, **OCS**=oral corticosteroids, **OMOP**=Observational Medical Outcomes Partnership, **wAIHA**=warm autoimmune hemolytic anemia.

Patient Characteristics

Baseline characteristics		wAIHA population (N=2028)	Rituximab cohort (N=613)
Demographics			
	Median (IQR) age at diagnosis index, y	62.0 (48.0-74.0)	61.0 (46.0-73.0)
	Female	59%	54%
	Race		
	Asian	2%	2%
	Black	12%	14%
	White	86%	84%
	Hispanic or Latino	7%	7%
Disease characteristics			
	Median (IQR) duration of follow-up, y	2.2 (1.4-3.3)	2.5 (1.8-3.7)
	Secondary wAIHA	45%	50%
	Lymphomas and leukemias	26%	40%
	Solid tumors	16%	15%
	Autoimmune disease	14%	12%
	Congenital immunodeficiencies	14%	17%
	Charlson Comorbidity index score		
	0	38%	30%
	1-2	32%	32%
	≥3	31%	38%

The characteristics of patients treated with rituximab were broadly similar to those of the overall wAIHA population

IQR=interquartile range, **wAIHA**=warm autoimmune hemolytic anemia.

Treatment Patterns: First-Line Maintenance Therapies for wAIHA During the Pooled 12-Month Follow-up Period

	Overall (N=2028)	Primary wAIHA (N=910)	Secondary wAIHA (N=1118)
Treatment status			
Untreated	29.0%	23.8%	33.3%
Treated	71.0%	76.2%	66.7%
Treatment received	(N=1439)	(N=693)	(N=746)
OCS monotherapy	64.1%	58.4%	69.4%
Rituximab monotherapy	15.3%	17.2%	13.5%
OCS + rituximab	12.6%	14.1%	11.1%
Immunosuppressant monotherapy[a]	3.0%	4.9%	1.2%
OCS + immunosuppressant	3.1%	3.0%	3.1%
Other[b]	1.9%	2.3%	1.6%

- In the first year after diagnosis, 23.8% of patients with primary wAIHA and 33.3% with secondary wAIHA did not receive any condition-specific treatment
- OCS monotherapy was the most frequent first-line maintenance therapy for both primary and secondary wAIHA
  - The percentage was higher for patients with secondary wAIHA
- First-line treatment heterogeneity suggests the continued need for standard guidelines

[a]Includes azathioprine, cyclosporine, cytotoxic therapy, cyclophosphamide, mycophenolate mofetil/mycophenolic acid, and tacrolimus.
[b]Includes alemtuzumab, bortezomib, danazol, and fostamatinib. **OCS**=oral corticosteroids, **wAIHA**=warm autoimmune hemolytic anemia.

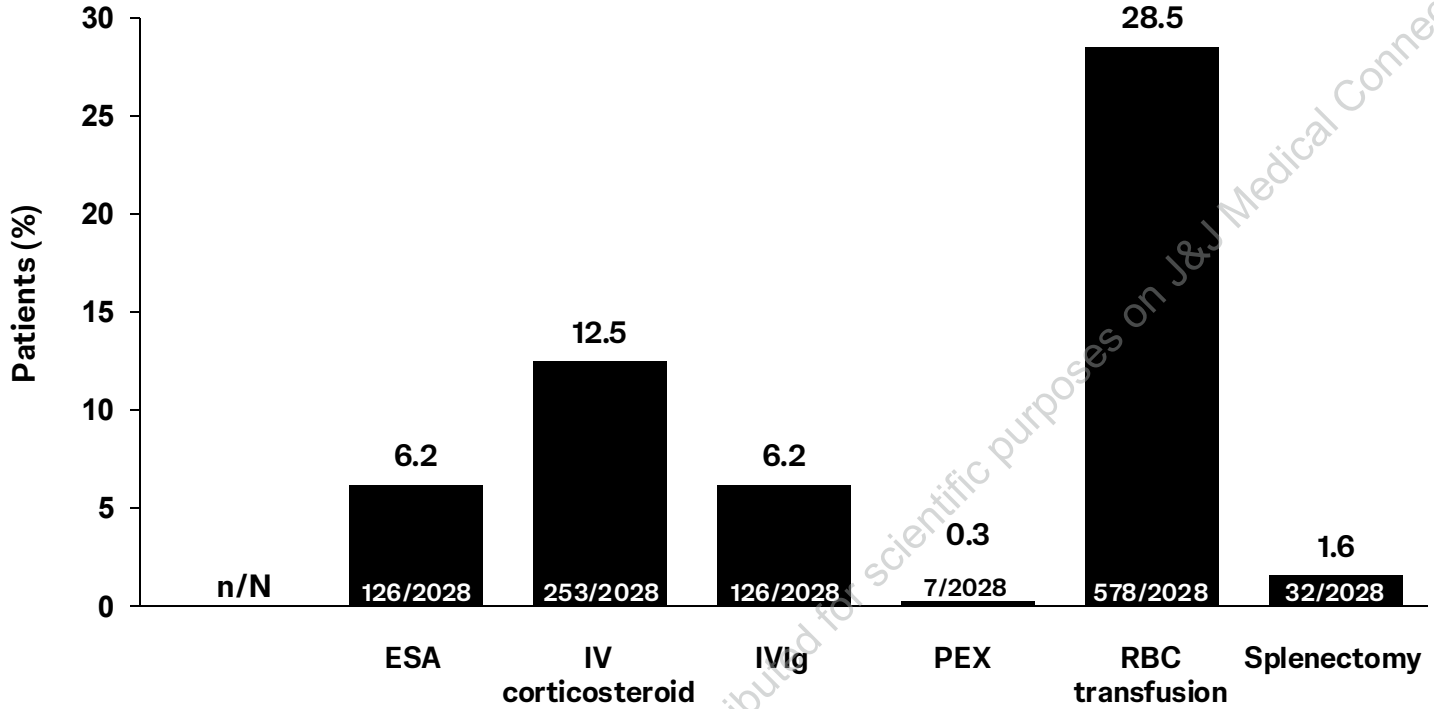
Treatment Patterns: Characteristics of the First Course of Rituximab Across All Lines of Therapy

	Patients (N=613)	Median administrations per course	Median course duration, d
Rituximab course type			
Complete 4-infusion regimen[a]	36.9%	4	21
Complete 2-infusion regimen[b]	0.5%	2	15
Incomplete 4-infusion regimen[a]	23.8%	3	14
Single infusion	12.9%	1	0
>4-infusion regimen[c]	24.8%	8	106

- The median time from baseline[d] to the first rituximab course was 59 days
- Among the 613 wAIHA patients who received rituximab therapy
  - Evidence-driven regimens were completed by 37.4% of patients (2 or 4 infusions)
  - 23.8% of patients received incomplete regimens
  - Nonstandard regimens were received by 37.7% of patients (single infusion or >4 infusions)

[a]Regimen consisted of 4 doses within 42 days. [b]Regimen consisted of 2 doses ≤21 days apart with ≥15 days between doses. [c]Regimen consisted of >4 doses without a gap of >90 days between doses. [d]Baseline date defined as 30 days before diagnosis. **wAIHA**=warm autoimmune hemolytic anemia.

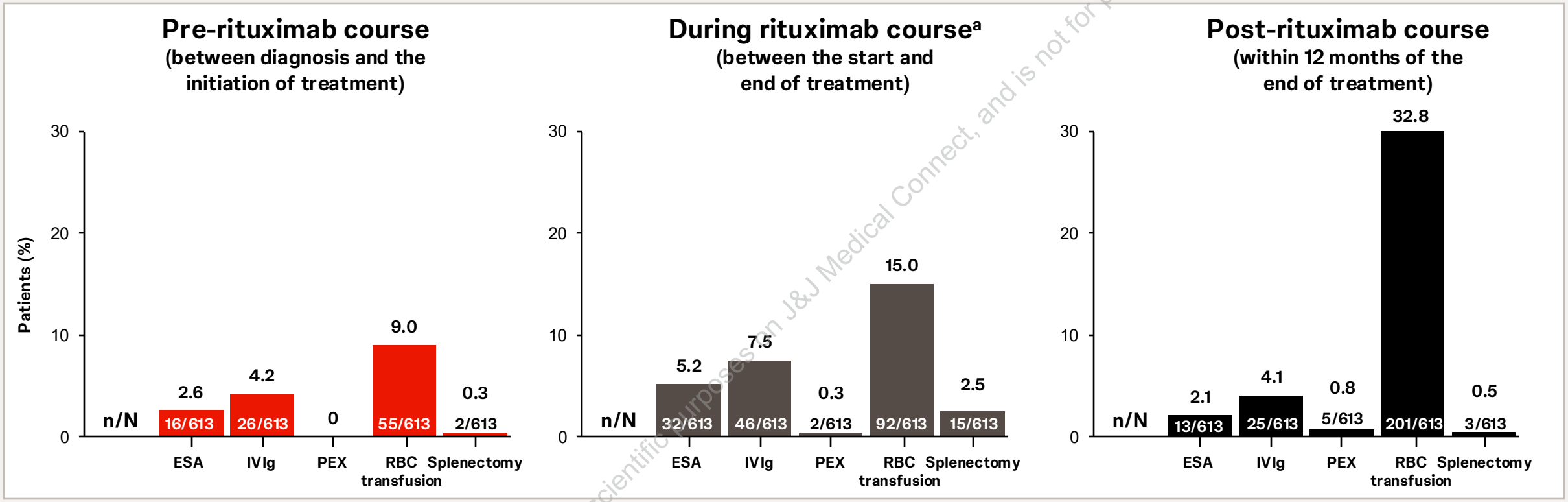
Use of Rescue Therapies Within the 12 Months Following wAIHA Diagnosis



- In the overall wAIHA population (N=2028), 55.3% of patients received ≥1 rescue therapies, and 28.5% of patients required an RBC transfusion within the 12 months following the wAIHA diagnosis
  - 6.2% of patients were treated with ESAs, with a median of 8.0 injections per patient
  - 6.2% of patients were treated with IVIg, with a median of 4.0 infusions per patient

ESA=erythropoiesis-stimulating agent, **IV**=intravenous, **IVIg**=intravenous immunoglobulin, **PEX**=plasma exchange, **RBC**=red blood cell, **wAIHA**=warm autoimmune hemolytic anemia.

Use of Rescue Therapies Before, During, and After Rituximab Treatment



- Among patients treated with rituximab (N=613), RBC transfusion was used more frequently after the rituximab course
  - The use of blood transfusions increased from 9.0% prior to rituximab treatment to 32.8% within 1 year following the final infusion of rituximab

[a]Each course was defined as period of continuous rituximab usage with <90 days gap. **ESA**=erythropoiesis-stimulating agent, **IVIg**=intravenous immunoglobulin, **PEX**=plasma exchange, **RBC**=red blood cell.

HCRU Within the First 12 Months of wAIHA Diagnosis

	All-cause	Anemia specific[a]
≥1 outpatient visit		
Patients	98%	62%
Median (IQR) number of visits per patient	31 (17-53)	4 (2-9)
≥1 emergency department visit		
Patients	38%	15%
Median (IQR) number of visits per patient	2 (1-3)	2 (1-2)
≥1 overnight hospitalization		
Patients	35%	23%
Median (IQR) number of events per patient	1 (1-3)	1 (1-2)
Median (IQR) length of stay, d	4 (2-8)	4 (2-9)

- In the overall wAIHA population (N=2028), nearly all patients (98%) had multiple outpatient visits
  - A median of 31 outpatient visits per patient was recorded over 12 months
- 38% of patients had ≥1 emergency department visit
- 35% of patients required ≥1 overnight hospitalization
  - Two-thirds were related to anemia[a]
  - The median length of stay was 4 days

[a]Related to ICD-10-CM Diagnosis Code D59.1*. **HCRU**=healthcare resource utilization, **ICD-10-CM**=*International Classification of Diseases, 10th Revision, Clinical Modification*, **IQR**=interquartile range, **wAIHA**=warm autoimmune hemolytic anemia.

Key Takeaways

Despite frequent use of rituximab, high HCRU and a high rate of rescue therapy use highlight persistent treatment gaps and the need for standardized US-based guidelines, implementation practices, and targeted options for the treatment of wAIHA

- ✓ Heterogeneity in rituximab dosing patterns, including high deviation from standard dosing practices, was observed, suggesting a continued need for standardized guidelines and implementation practices

- ✓ Despite current treatment options, more than half of patients required rescue therapy, with 1 in 4 requiring an RBC transfusion in the first year following the wAIHA diagnosis
- ✓ Despite rituximab treatment, transfusion use was high during the 12-month period post rituximab, with 1 in 3 patients receiving transfusions

- ✓ The HCRU burden for patients with wAIHA is substantial, with 1 in 3 patients requiring overnight hospitalization in the first year after diagnosis and a similar proportion with emergency department visits

HCRU=healthcare resource utilization, **RBC**=red blood cell, **wAIHA**=warm autoimmune hemolytic anemia.

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