Managing Lymphoma

CLL in Rural America:
A Cancer Care Performance and Quality Improvement Initiative for Clinicians in Rural Practice

Provided by
MediCom Worldwide, Inc.

Supported by educational grants from AbbVie, Genentech, and Pharmacyclics.

1

Managing Lymphoma

Rural Cancer Care Nationally and Locally

Alan Morgan, MPA
Chief Executive Officer
National Rural Health Association
Washington, DC

2

The State of Rural America

- Workforce shortages
- Vulnerable populations
- Chronic poverty

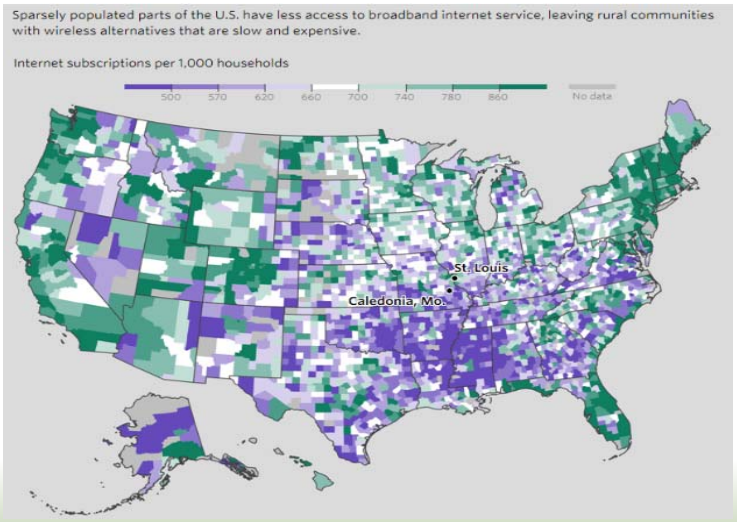
3

Workforce Shortages

- Only 9% of physicians practice in rural America
- 77% of the 2,050 rural counties are primary care Health Professional Shortage Areas (HPSAs)
- More than 50% of rural patients have to drive 60+ miles to receive specialty care

4

Less Broadband Access



Source: *Wall Street Journal*

5

The Pre-COVID Rural Hospital Environment

- In February 1, 2020:
  - 2000 rural hospitals (1300 Critical Access Hospitals, 700 Prospective Payment System Facilities)
  - 47% operating at a loss
  - Half of all rural hospitals had 30 days cash on hand
  - More than 400 at risk for closure

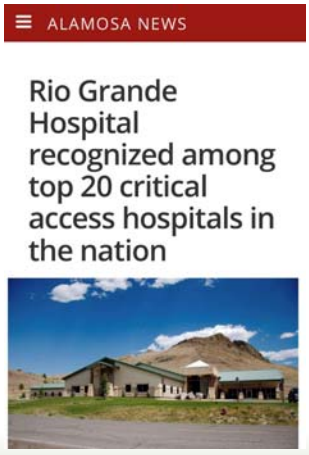
6

"Coronavirus strains cash-strapped hospitals, could cause up to 100 to close within a year"

Josh Salman and
Jayme Fraser
USA TODAY NETWORK

7

However, Rural Excellence Exists



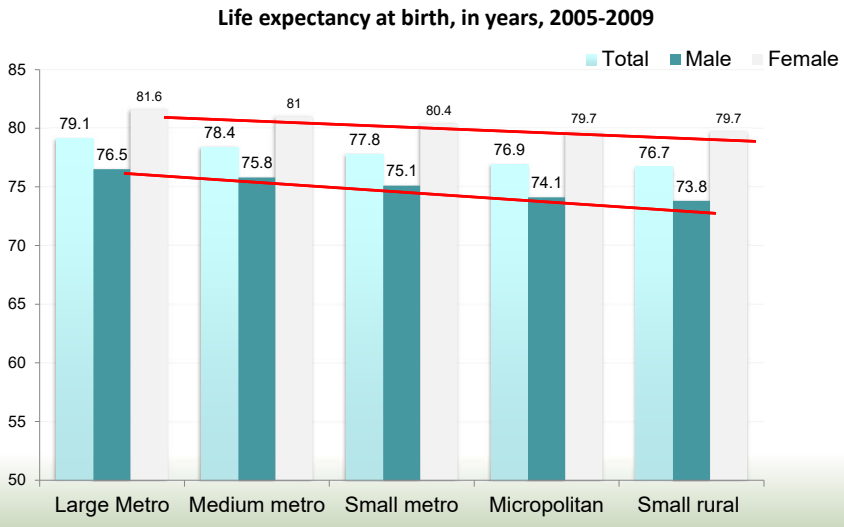
8

Rural as an Older, Sicker and Poorer Population

- The median age of adults living in rural areas is greater than those living in urban
  - Rural: 51 years
  - Urban: 45 Years
- 18.4% of rural residents are age 65+, whereas its 14.5% in urban
- Rural areas have higher rates of several health risk factors/conditions
  - Obesity
  - Diabetes
  - Smoking

9

Life Expectancy Declines with Rurality



Singh GK, Siahpush M. *J Urban Health.* 2014;91(2):272-292.

10

Rural Cancer Mortality Rates
A Rural Divide in American Death: CDC 2017

- Rates of cancer are higher among rural Americans
- Minorities, especially Native Americans, die consistently prematurely – more pronounced in rural

11

Rural Cancer Rates

- Reported death rates were higher in rural areas (180 deaths per 100,000 persons) compared with urban areas (158 deaths per 100,000 persons)
- Analysis indicated that while overall cancer incidence rates were somewhat lower in rural areas than in urban areas, incidence rates were higher in rural areas for several cancers: those related to tobacco use such as lung cancer and those that can be prevented by cancer screening such as colorectal and cervical cancers
- ***While rural areas have lower incidence of cancer than urban areas, they have higher cancer death rates. The differences in death rates between rural and urban areas are increasing over time***

Centers for Disease Control and Prevention, MMWR Series July 2017.

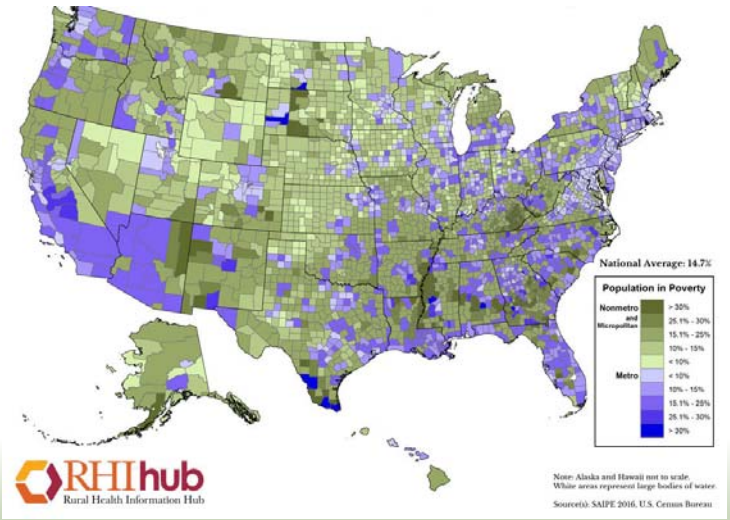
12

Cancer Care: Rural is NOT a Small Version of Urban

- **Barriers to accessing cancer care services** (financial hardships, such as being underinsured or uninsured; shortage of physicians; oncology specialists; distance from treatment facilities; no personal vehicle and/or lack of access to public transportation to reach services; prejudice/discrimination)
- **Rural specific environment programs** and policies to improve care and access to treatment services in rural areas may interact with the implementation of the intervention and potentially influence effectiveness
- **Role of social determinants of health**, including socioeconomic factors, cultural differences that influence trust in and attitudes toward institutions, medical providers, and government-sponsored programs

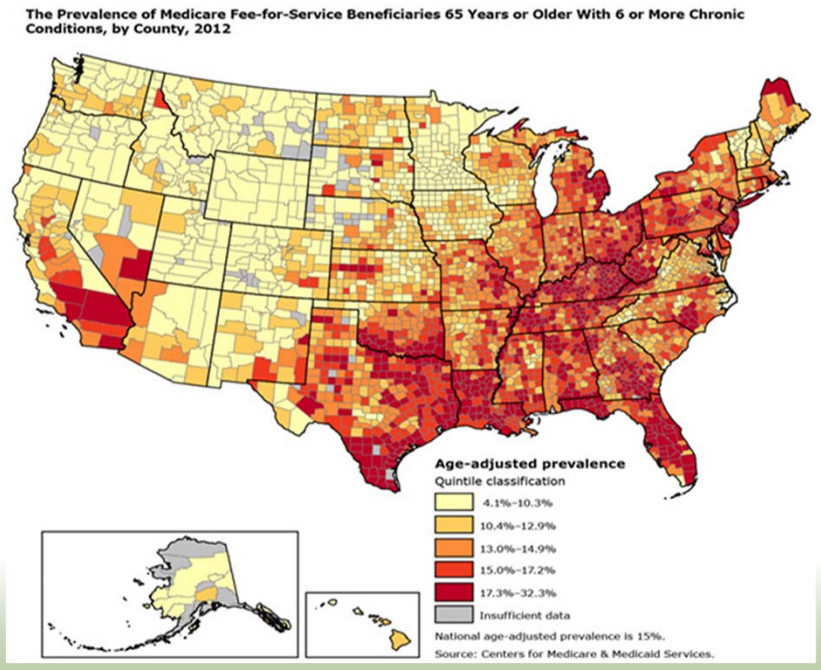
13

Population in Poverty by County



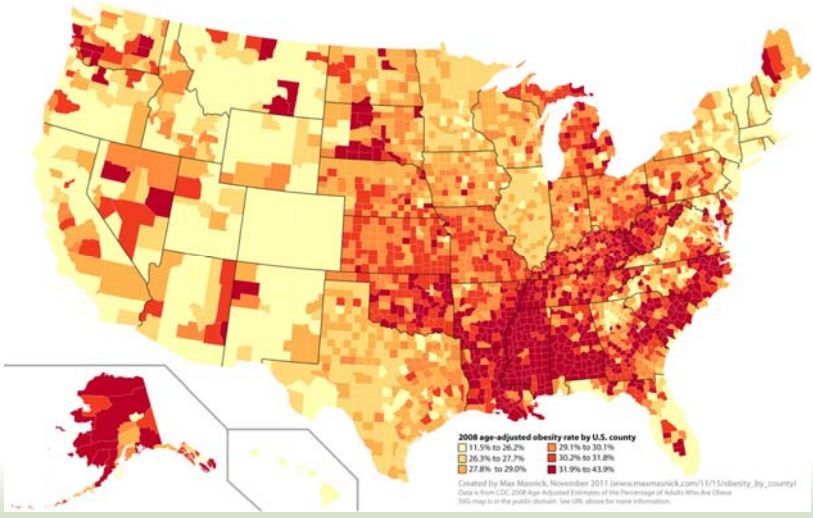
14

Prevalence of Medicare Patients with Six or More Chronic Conditions



15

Obesity



16

A (Short) History of Rural Health

- War on Poverty in the 60s
- Community Health Centers, created in the War on Poverty
- Rural Health Clinics –38 Years Old (1978), 4,100 nationwide
- Result of PPS 1983: 440 hospital closures
- Policy Response 1992-2003:
  - State Office of Rural Health (SORH
  - Medicare Dependent Hospitals (MDH)
  - Critical Access Hospital (CAH) 1997
  - Medicare Rural Flexibility Program (1997)
  - Low-Volume Hospital (LVH) Adjustment (2003 and 2010)
- Patient Protection and Affordable Care Act (ACA) 2010
- Medicare Access and Chip Reauthorization Act (MACRA) 2015

17

Shift to New Payment Models/Delivery of Care

Older Models

- Frontier Extended Stay Clinic (FESC)
- Frontier Community Health Integration Project (F-CHIP)
- Rural Community Hospital Demonstration Program

Newer Models

- Global Budget Model
  - Sen. Bob Casey (D-PA)
- 24/7 ER Model with Cost-Based Reimbursement
  - Community Outpatient Hospital
  - REACH ACT

18

Managing Lymphoma

Treatment of CLL: Current and Emerging Approaches

Farrukh T. Awan, MD
Associate Professor of Medicine
Director of Lymphoid Malignancies Program
University of Texas Southwestern Medical Center
Dallas, Texas

19

Objectives

- Introduction and prognostic testing
- Frontline treatment
- Treatment in the relapsed setting

20

CLL is the Most Prevalent Cancer in the Western Hemisphere

- Around 200,000 survivors
- Median age at diagnosis is 71 years
- Men twice as likely
- 80% are asymptomatic

American Cancer Society. https://www.cancer.org/cancer/chronic-lymphocytic-leukemia/detection-diagnosis-staging/signs-symptoms.html.

21

Definition of CLL: iwCLL – 2008/2018

- Small, monomorphic, mature B-cells
- At least 5,000/ul circulating B-cells
- Co-express CD5 and CD23 (need flow cytometry to diagnose)

Hallek M, et al. *Blood*. 2018;131 (25):2745-2760.

22

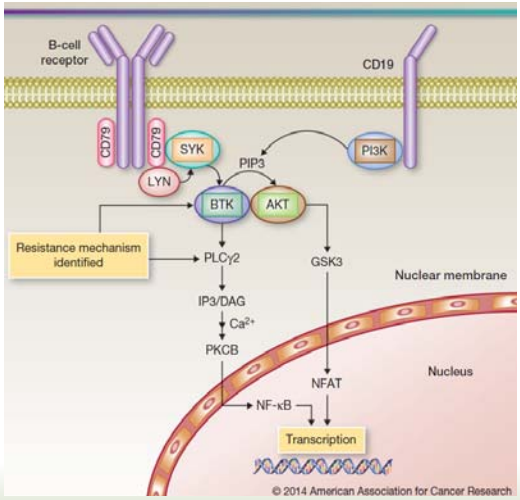
Timing of Therapy

- Constitutional symptoms – How do you feel?
  - Unintentional weight loss of >10% within the previous 6 months
  - Significant fatigue (ECOG PS 2 or worse)
  - Fevers >100.5°F for >2 weeks without other evidence of infection
  - Night sweats for >1 month without evidence of infection
- Objective signs – How are the numbers?
  - Worsening or steroid resistant anemia (<11) and/or thrombocytopenia (<100)
  - Spleen >6 cm below the left costal margin
  - Lymph nodes >10 cm

Hallek M, et al. *Blood*. 2018;131 (25):2745-2760.

23

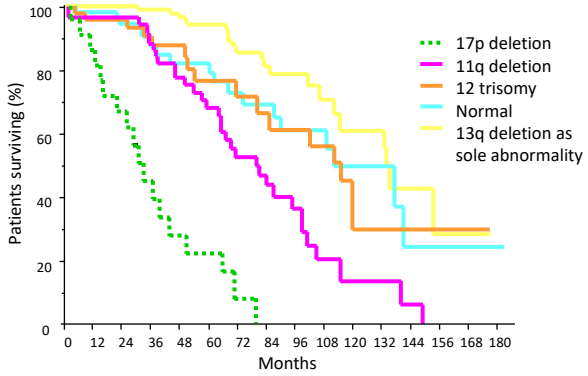
Targeting BCR in CLL



PI3K=phosphoinositide 3-kinase; SYK=spleen tyrosine kinase; BTK=Bruton tyrosine kinase; PIP3=phosphatidylinositol–3,4,5,-triphosphate; DAG=diacylglycerol; PKC=protein kinase; GSK=glycogen synthase kinase; NFAT=nuclear receptor of activated T cells; NF-κB=nuclear factor kappa-light-chain-enhancer of activated B cells.
Awan FT, Byrd JC. *Clin Cancer Res.* 2014;20:5869-5874.

24

CLL: Prognostic Value of FISH



Abnormality detected by FISH	Median Time to Treatment (months)	Median Overall Survival (months)	Percentage of Patients (%)
Del 17p	9	32	7
Del 11q	13	79	18
Trisomy 12	33	114	16
Del 13q	49	133	55
Normal	92	111	18

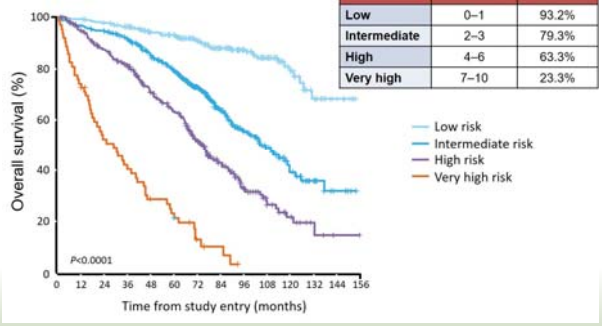
Dohner, et al. *N Engl J Med*. 2000;343(26):1910-1916.

25

CLL IPI Score – Predicts Survival

Prognostic Factor	Adverse Factor	Risk Score
Age	>65 years versus ≤65 years	1
Binet B/C or Rai III–IV	Yes	1
Beta-2 microglobulin	>3.5 mg/L versus ≤3.5 mg/L	2
IGHV	Unmutated	2
TP53 status	Deletion 17p (FISH) and/or TP53 mutation	4

Risk Level	Risk Score	5-Year OS
Low	0–1	93.2%
Intermediate	2–3	79.3%
High	4–6	63.3%
Very high	7–10	23.3%



CLL IPI=Chronic Lymphocytic Leukemia International Prognostic Index.
International CLL-IPI working group. *Lancet Oncol*. 2016;17:779-790.

26

Objectives

- Introduction and prognostic testing
- Frontline treatment
- Treatment in the relapsed setting

27

Chemo-Immunotherapy

PROS

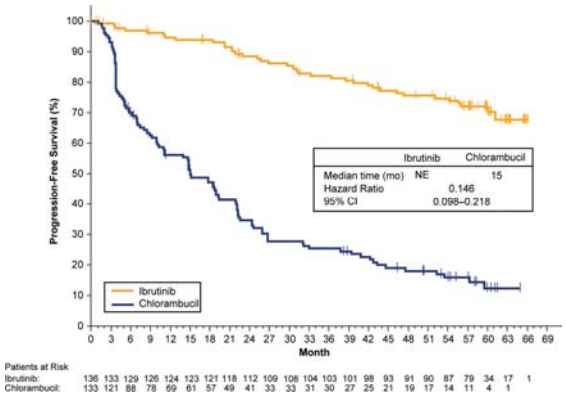
- Tried and tested
- Long-term data available
- Fixed duration
- In this era, may be the cheapest option

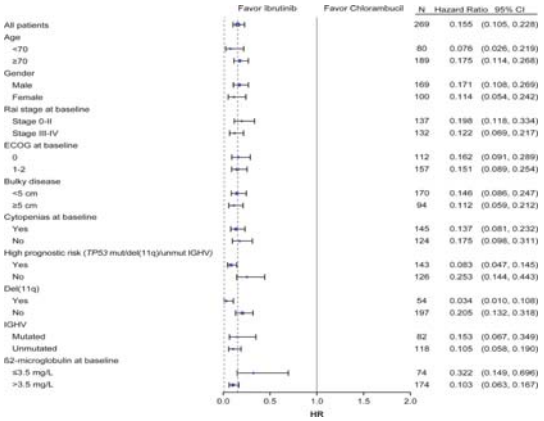
CONS

- Side effects
- Not suitable for all patients
- Bone marrow stem cell damage
- Immunosuppressive

28

RESONATE-2 Extended 5-Year Follow-up: PFS



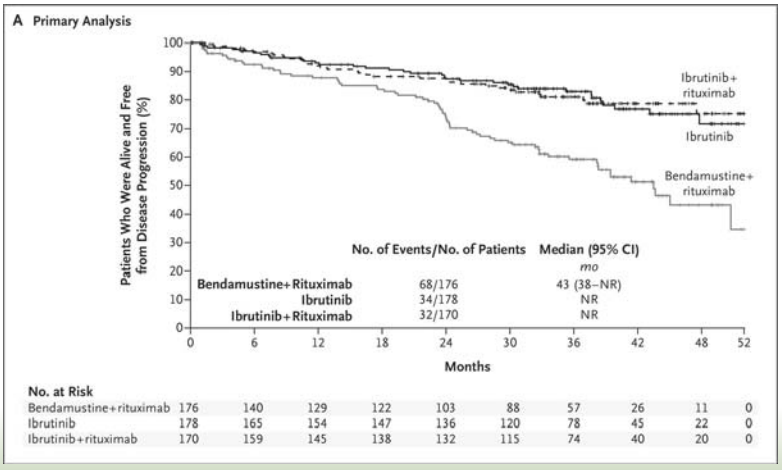


- 21 patients on ibrutinib arm progressed during follow-up; 8 while actively on treatment
- PFS benefit with ibrutinib maintained across all subgroups evaluated including age, ECOG PS, Rai stage, and bulky disease

Burger A, et al. *Leukemia.* 2020;34(3):787-798.

29

Ibrutinib vs. Chemoimmunotherapy:
Alliance Trial – BR vs I vs IR: Frontline, Older Patients



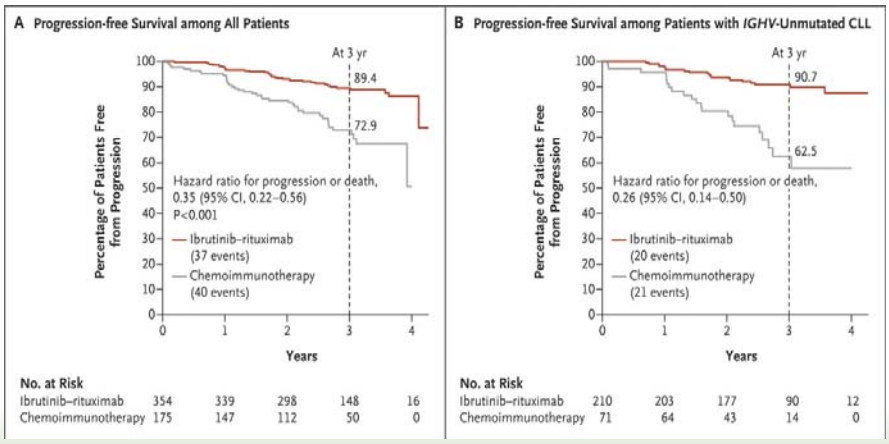
Primary Endpoint: PFS
BR: mPFS 43 mos
Ibr: mPFS NR
Ibr+R: mPFS: NR

No difference in PFS ibrutinib vs ibrutinib + R

Woyach JA, et al. *N Engl J Med*. 2018;379:2517-2528.

30

Ibrutinib vs. Chemoimmunotherapy: PFS
Frontline, Younger Patients (EA1912)

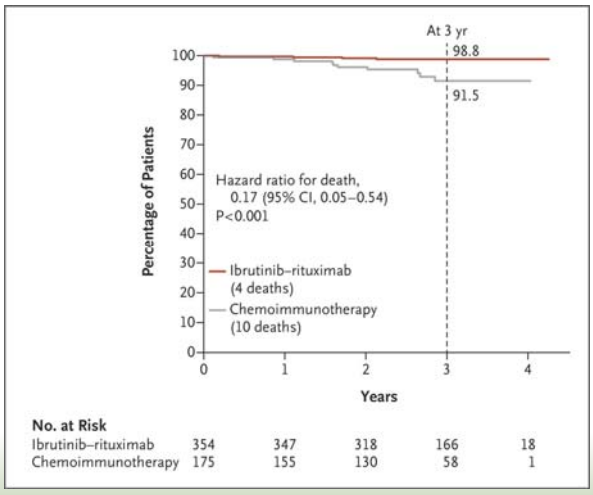


3-year PFS 89.4% for IR and 72.9% for FCR
(HR=0.35; 95% CI 0.223-0.558; *P*<0.0001)

Woyach JA, et al. *N Engl J Med*. 2018;379:2517-2528.

31

Ibrutinib vs. Chemoimmunotherapy: Overall Survival
Frontline, Younger Patients (EA1912)

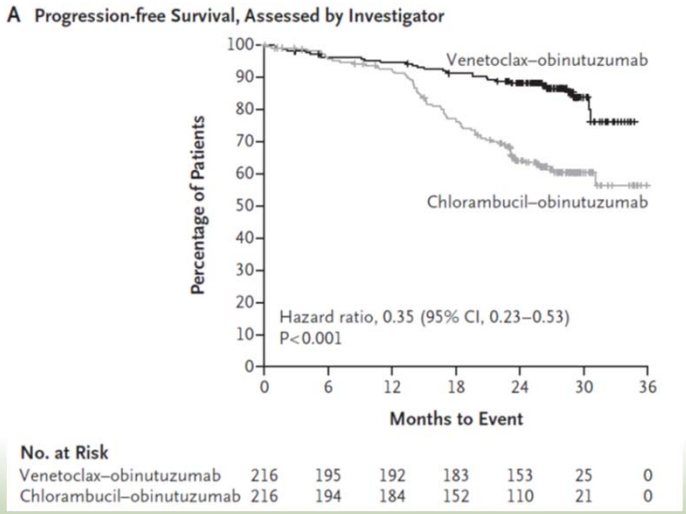


3-year OS was 98.8% for IR and 91.5% for FCR
(HR=0.168, 95% CI 0.053-0.538; *P*=0.0003)

Woyach JA, et al. *N Engl J Med*. 2018;379:2517-2528.

32

Ven/Obin for Frontline CLL: CLL14 - PFS



mFollow-up: 28 months

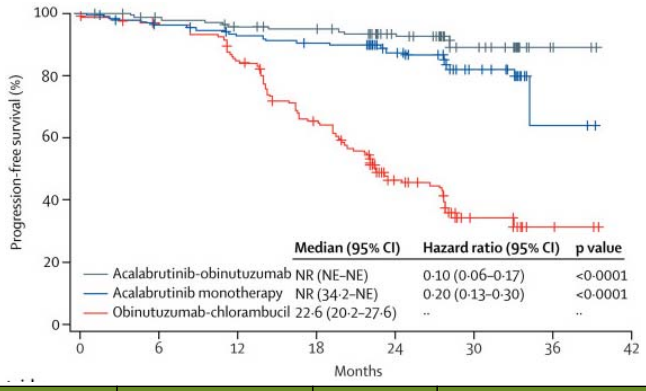
mTime off treatment: 17 months

24-month estimate of PFS
venG: 88%
G-chlor: 64%

Fischer K, et al. *N Engl J Med*. 2019;380:2225-2236.

33

ACE-CL-007 (ELEVATE-TN) Phase 3 Study in Untreated CLL: PFS

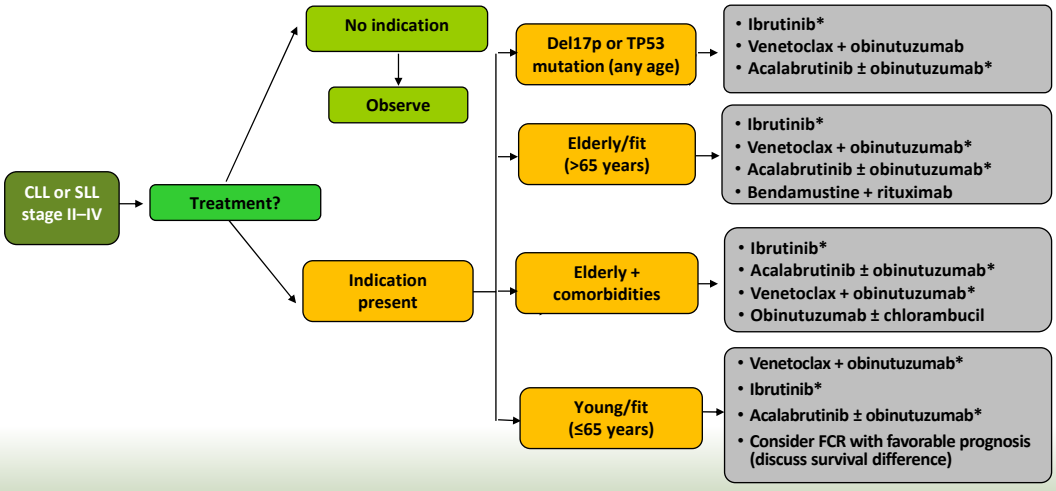


	A+O (N=179)	A (N=179)	C+O (N=177)
Events, n (%)	14 (7.8)	26(14.5)	93 (52.5)
Median PFS (m)	NR	NR	22.6 (95% CI: 20.2-27.6

Median follow-up: TOTAL: 28.3 mo; GC[a] 28.0 mo; AG: 28.5 mo; A 28.4 mo
Sharman JP, et al. *Lancet*. 2020;395(10232):1278-1291.

34

Summary of Frontline Therapy



*preferred
SLL=small lymphocytic lymphoma

35

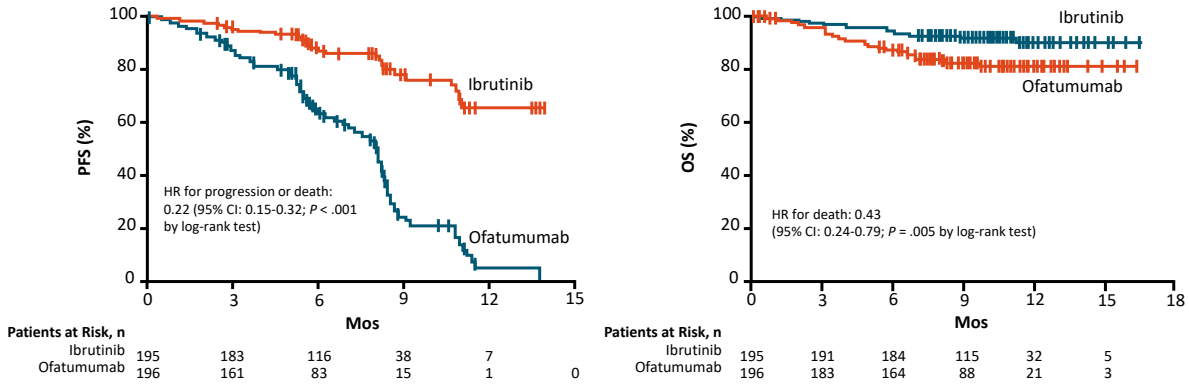
Objectives

- Introduction and prognostic testing
- Frontline treatment
- Treatment in the relapsed setting

36

36

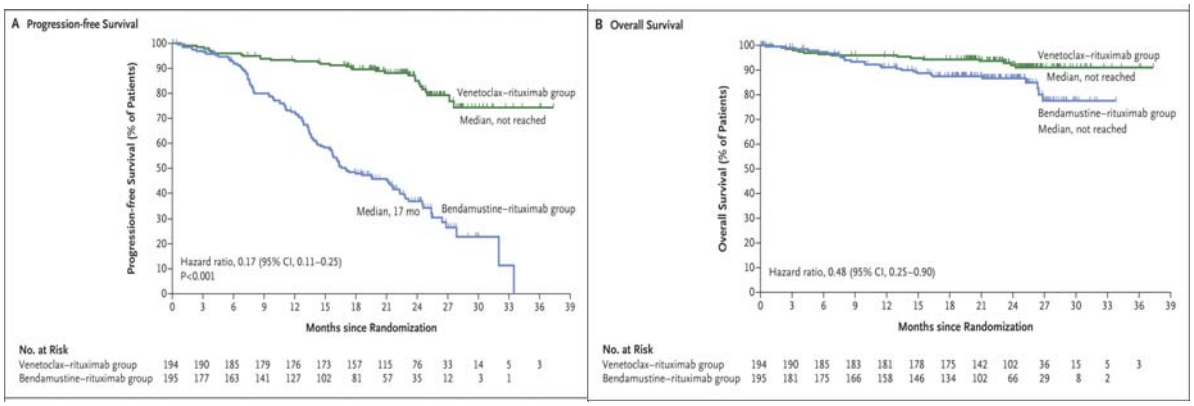
RESONATE Trial: Ibrutinib vs Ofatumumab in Relapsed CLL/SLL



Byrd JC, et al. *N Engl J Med*. 2014;371:213-223.

37

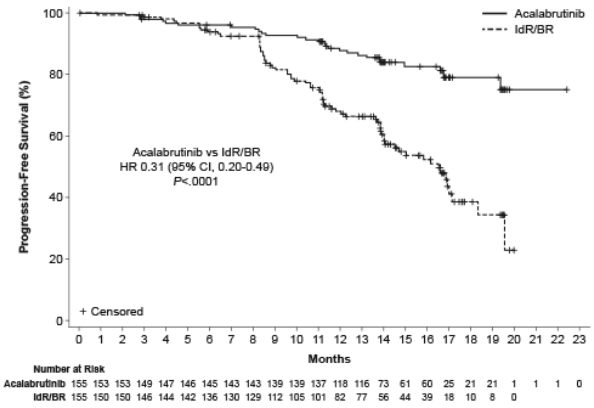
Venetoclax and Rituximab Is Better Than BR



Seymour JF, et al. N *Engl J Med*. 2018;378:1107-1120.

38

ACE-CL-009 (ASCEND) Phase 3 Study in R/R CLL: PFS

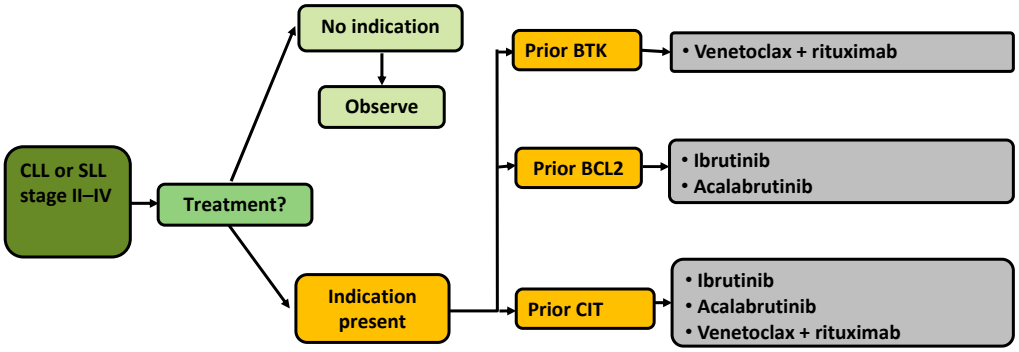


	Acalabrutinib	BR/IR
Progression free at 12m	87.8	68
Progression free at 15 m	82.6	54.9
Progression free at 18	79	38.6

Median follow-up 16.1 mo in acalabrutinib and 15.7 mo in ARM B
Median duration of treatment for acal 15.7 (1.1, 22.4);
IR: ide 11.5 (0.1, 21.1) rituximab 5.5 (0.9, 8.5);
BR: benda 5.6 (1.0, 7.1), rituximab 5.5 (0.9, 7.1)
EHA, ASH: 2019

39

Summary of Relapsed Treatment



40

Conclusions

- Prognostic assessment is critical for patients with CLL prior to starting therapy
- Chemotherapy-based treatments have limited role in CLL
- Sequencing and patient factors are important
- Patient education and input is essential in deciding course of action

41

Managing Lymphoma

CMS/MIPS Performance and Quality Improvement in Rural Practice

Opal H. Greenway, JD
Stroudwater Associates
Nashville, Tennessee

42

Overview

- Rural Cancer Care Resource Guide
- The Centers for Medicare & Medicaid Services Quality Payment Program for Small, Underserved, and Rural Practices
- MIPS Performance and Quality Improvement Worksheet

43

Rural Cancer Care Resource Guide

- Rural Practice and CLL-Specific Education and Resources
- The Centers for Medicare & Medicaid Services (CMS) Quality Payment Program (QPP) for Small, Underserved, and Rural Practices
- CMS/QPP Resource Library
- MIPS Performance and Quality Improvement Documentation Worksheet

44

The Centers for Medicare & Medicaid Services Quality Payment Program for Small, Underserved, and Rural Practices

- Free, customized technical assistance
- Support is available to small practices with 15 or fewer clinicians
- Priority is given to small practices located in

45

Program-Level Support

- Understanding the general requirements of the QPP
- Determining if you're included in the program
- Choosing appropriate MIPS measures and activities to report
- Submitting data
- Transitioning into an Alternative Payment Model (APM) or Advanced APM

South Dakota:
Telligen qpp-surs@telligen.com
1-844-358-4021

46

Practice-Level Support

- Assessing practice readiness
- Implementing certified electronic health record technology (CEHRT)
- Forming partnerships with peers, local stakeholders, regional collaboratives, and more
- Participating in a quality improvement initiative

47

Merit-Based Incentive Payment System (MIPS)

- Under MIPS, CMS evaluates the performance of clinicians across four performance categories:

Quality (45%)	Cost (15%)	Improvement Activities (15%)	Promoting Interoperability (25%)

- Scores are added together to produce a MIPS final score
- Your MIPS final score will determine whether you receive a negative, neutral, or positive **MIPS payment adjustment**

48

Overall Flexibilities for Small, Underserved, and Rural Practices

- Exclude clinicians or groups with
  - ≤$90,000 in allowed charges for covered professional services under the Medicare Physician Fee Schedule (PFS)
  - ≤200 Medicare Part B patients who are furnished covered professional services under the Medicare PFS
  - ≤200 covered professional services under the Medicare PFS
- Give solo practitioners and practices with 10 or fewer clinicians the choice to form a **virtual group** to participate with other practices

49

Overall Flexibilities for Small, Underserved, and Rural Practices

- Allow clinicians in small practices to submit data for the Quality performance category through Medicare Part B claims for covered professional services at both the
  - Individual level
  - Group level

50

Reporting Requirements for the Quality Performance Category

6 Quality measures

- Including at least 1 outcome measure or high-priority measure in absence of an applicable outcome measure; OR

A defined specialty measure set or sub-specialty measure set

- If the measure set has fewer than 6 measures, you need to submit all measures within that set; OR

All quality measures included in the CMS Web Interface

51

Reporting Requirements for the Quality Performance Category

Collection types

- Electronic Clinical Quality Measures (eCQMs)
- MIPS Clinical Quality Measures (CQMs)
- Qualified Clinical Data Registry (QCDR) measures
- Medicare Part B claims measures
- CMS Web Interface measures
- The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey

52

Quality Flexibilities for Small, Underserved, and Rural Practices

- If you are in a small practice, you will be awarded
  - **3 points** in the Quality performance category for measures that don't meet data completeness requirements
  - **6 bonus** points in the Quality performance category if you submit at least one Quality measure

53

Improvement Activities Flexibilities for Small, Underserved, and Rural Practices

- Small practices, especially those in rural locations and HPSAs, are required to report only **2 activities** in the Improvement Activities performance category
- If you are in a small practice or located in a rural area or HPSA, you will earn **double the points** for each activity you submit:

Medium-weighted activity = 20 points	High-weighted activity = 40 points

54

Reporting Requirements for the Promoting Interoperability Performance Category

- e-Prescribing
- Provider to Patient Exchange
- Health Information Exchange
- Public Health and Clinical Data Exchange

- Within these objectives, there **are 6 required measures** in addition to **required attestations**

55

Reporting Requirements for the Promoting Interoperability Performance Category

- For PY 2020, clinicians must collect data for each measure for a minimum of 90 continuous days using **2015 Edition CEHRT**

OR

- Submit a **Hardship Exception Application** to have the Promoting Interoperability category reweighted to 0%

56

Promoting Interoperability Flexibilities for Small, Underserved, and Rural Practices

- You may submit a **Hardship Exception** Application because you

Are in a small practice

Have insufficient internet connectivity

Have extreme and uncontrollable circumstances

Lack control over your availability to CEHRT

Are using decertified EHR technology

57

Policy for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- You may be exempt from MIPS
- If you bill for Medicare Part B services exclusively through the RHC or FQHC payment methods, you are not eligible for payment adjustments under MIPS
- If you are a part of an RHC or FQHC and bill for Medicare Part B services under the PFS, payment for such other services would be subject to the MIPS payment adjustments
  - Unless your billings are below the low volume threshold or you meet another exclusion

58

Policy for Critical Access Hospitals (CAHs)

- You may be eligible to participate in MIPS
- If you practice in a **Method I CAH**, the payment adjustment would apply to services you bill under the PFS, but not to the facility payment
  - The payment adjustment works the same way if you practice in a Method II CAH but have not assigned billing rights to the CAH
- If you practice in a **Method II CAH** and have assigned billing rights to the CAH, the payment adjustment would apply to the Method II CAH payments

59

MIPS Performance and Quality Improvement Documentation Worksheet

2020 Quality Performance Category

- General reporting requirements
- Flexibilities for small, underserved, and rural practices
- Choosing your Quality measures

2020 Improvement Activities Performance Category

- Flexibilities for small, underserved, and rural practices
- Reporting CME activities to fulfill MIPS requirements for the Improvement Activities performance category

60