NCCN Best Practices Committee
Infusion Efficiency Workgroup

Toolkit: Providing Oncology Treatments in the Outpatient Setting

Revised: 03/31/2020
Executive Summary

• This Toolkit was originally developed in 2019 to provide guidance to cancer centers seeking to transition chemotherapy regimens from the inpatient to the outpatient setting.

• Amid the current COVID-19 crisis, shifting to alternate sites of care can help maximize inpatient bed availability while providing high quality, safe cancer care without significant delays.

• All regimens in this Toolkit are currently being provided in the outpatient setting at one or more NCCN Member Institutions.
In 2015, NCCN formed an Infusion Efficiency Workgroup to study capacity and efficiency challenges faced by many cancer centers, and to recommend best practices for operating efficient and effective cancer centers while maintaining high patient safety standards. The Workgroup operates under the auspices of the NCCN Best Practices Committee, which focuses on enhancing cancer center operations. The Workgroup’s early work consisted of collecting data regarding average patient wait time in infusion centers, chemotherapy premixing practices, infusion chair utilization, and premedication protocols. It was found that there is a high degree of variation among cancer centers in regards to planned chair time for the same chemotherapy regimens, providing opportunities for improved efficiency, increased revenue, and more standardization across centers. The Workgroup demonstrated potential revenue impact and provided recommendations for cancer centers to move towards more efficient and more standard practices (Ref 1: Sugalski J, Kubal T, et al: National Comprehensive Cancer Network Infusion Efficiency Study: Optimizing Patient Flow in Infusion Centers, Journal of Oncology Practice (online April 9, 2019; doi:10/1200/JOP.18.00563)).

In 2018, the Infusion Efficiency Workgroup focused on looking ahead to consider what the ideal future infusion center might look like. Recent trends indicated a shift of treatments to the outpatient and home setting. The Workgroup conducted a survey to determine in which setting (inpatient, outpatient, or home) cancer centers are currently providing the majority of specific treatments, such as DA EPOCH, ICE, and HiDAC. This analysis again revealed much variation among cancer centers and identified an opportunity to develop best practices for providing certain treatments in the outpatient setting, which is the focus on this Toolkit.
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Toolkit Regimens

- Blinatumomab
- Cytarabine/Daunorubicin Liposome Induction
- Dose Adjusted EPOCH
- Gemtuzumab
- High-Dose Methotrexate
- High-Dose or Intermediate-Dose Cytarabine Consolidation
- HyperCVAD-Arm A
- ICE +/- Rituximab
- Inotuzumab
- MiniCVD Arm A + Inotuzumab
- Moxetumomab
- Tagraxofusp
Blinatumomab

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution.

Need for Caregiver
Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Required prior to outpatient administration.

If bag changes to occur with home health, both drug and home nursing approval required.

Labs for Chemo Clearance
CMP, CBC with diff.

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Inpatient stay required per package insert, please see known variability below. Preferred start time 9AM with labs drawn 1 hour prior.

Infusion center chair times must be consistent with start time of initial inpatient blinatumumab administration

Patient receives the entire Cycle 3+ outpatient:
Infusion center chair times are scheduled in the morning for the duration of this cycle.

Approximate Chair time 90 minutes.

Labs During Treatment
Individualized per patient:
CMP, CBC with diff.

Additional RN Assessments
Neuro assessment; according to institution policy.

APP and/or Clinical PharmD Assessments
Perform patient assessment in infusion center on days of blinatumumab bag change. Monitor for toxicities (mental status changes, need for transfusions/IVFs/electrolyte replacement). Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.

Miscellaneous
Infusion bag contains overfill. Do not flush line, see package insert. Pump battery changed every 3-4 days per institutional policy. If bag is held ≥4 hours, patient must receive additional premedication with dexamethasone per package insert.

Additional Staff Needed
Dedicated APP.

In-Home Delivery Possible
Yes, chemotherapy competency per institutional requirement.

Known Variability: Blinatumumab may be prepared via 24-hour, 48-hour or 7-day bag per package insert and institutional policy. Hospitalization is recommended for the first 3 days of Cycle 1 and the first 2 days Cycle 2 for patients with B-ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1%. Hospitalization is recommended for the first 9 days of Cycle 1 and the first 2 days of Cycle 2 for patients with relapsed or refractory B-ALL. The differences in length of hospitalization is related to the different dosing schemas and is in alignment with the package insert recommendations.
Cytarabine/Daunorubicin Liposome Induction

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Required prior to outpatient administration.

Labs for Chemo Clearance
CMP, CBC with diff.
MUGA/ECHO prior to Cycle 1

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer start times due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).

Approximate Chair time
135 minutes.

Labs During Treatment
Days 1-5: CBC with diff, CMP, uric acid, and phosphorus.

Additional RN Assessments
According to institutional policy.

APP and/or Clinical PharmD Assessments
Perform patient assessment on Days 1–5 to address any acute issues. Assess patient prior to chemotherapy administration on Days 1, 3, 5. Assess patient in infusion center or clinic on Days 2 and 4 after labs. Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.

Miscellaneous
Patient is admitted Day 6 through count recovery (consider local reimbursement challenges if present). If any patient complications arise (e.g., infections, fever, etc.) during Days 1-5, patient should be admitted.

Additional Staff Needed
Dedicated APP.

In-Home Delivery Possible
No.

Afterhours Troubleshooting
Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

Labs Post-Chemo
N/A (patient admitted to hospital).

Chemo Clearance Follow-up Considerations
N/A

Indications/Diagnosis Code
Acute Myeloid Leukemia (AML) with myelodysplastic related changes or Therapy related AML. C92.A0.

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.
Dose Adjusted EPOCH

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

Pre-Work

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Not Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Required prior to outpatient administration.

Labs for Chemo Clearance
CMP, CBC with diff.
MUGA/ECHO prior to Cycle 1.

Treatment

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer Monday morning start due to slight variability when chemo bag finishes to ensure completion occurs during infusion center hours.

Approximate Chair time

Labs During Treatment
None.

Additional RN Assessments
According to institution policy.

Infusion Center Pharmacy Assessments
Assess chemo bags on Days 2 - 4 to determine if rate change is needed.

APP and/or Clinical PharmD Assessments
Perform patient assessment in infusion center daily: Need for infusion rate adjustments for timely completion of chemo bags, toxicities (n/v, neuropathy, volume overload signs, GI issues, TLS). Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.

Miscellaneous
If intrathecal chemotherapy is required, prefer Day 1 administration to minimize complications with completion of chemo bags. High risk for febrile neutropenia; growth factor support provided per institutional policy and individual insurance. Pump battery changed every 3-4 days per institution policy.

Additional Staff Needed
Dedicated APP +/ PharmD.

In-Home Delivery Possible
Yes, chemotherapy competency per institutional requirement.

Post-Treatment

Afterhours Troubleshooting
Provide phone number for pump-specific issues and on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

Labs Post-Chemo
Twice weekly clinic visits to assess for cytopenias, aid with dose adjustment for subsequent cycles and monitor for transfusion needs.

Chemotherapy Clearance Follow-up Considerations
Chemotherapy clearance visit in clinic preferred on Thurs or Fri prior to subsequent cycle. Prefer to start Day 1 on Monday mornings.

Indications/Diagnosis Code
HIV associated lymphoma. Primary mediastinal lymphoma C85.20, Double hit and triple hit lymphoma C83.3, High risk Diffuse Large B-Cell Lymphoma C83.3, Burkitts lymphoma C84.48

Known Variability
First rituximab infusion is given at slow rate. If no infusion reactions experienced with prior rituximab cycle, a rapid infusion may be used per institutional availability. Day of rituximab infusion per institutional policy with Day 1, 5, 6 generally acceptable dates depending on duration of infusion. Subcutaneous Rituximab Hyaluronidase may be substituted for rituximab after patients receive first full dose of rituximab by intravenous infusion.
The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a healthcare delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

### Pre-Work

**Suitability for Outpatient Administration**
- Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.
- **Need for Caregiver**
  - Required.
- **Social Work Consult to Aid with Lodging/Transportation**
  - Required if patient needs assistance with local lodging and/or transportation.
- **Patient Education Provided by Pharmacist**
  - Required; see attached patient education example.
- **Specific Line (port vs PICC) Needed**
  - Central line per institutional policy.
- **Financial Clearance**
  - Required prior to outpatient administration.
- **Labs for Chemo Clearance**
  - CMP, uric acid, phosphorus, CBC with diff.

### Treatment

**Infusion Center Accommodations**
- Start dates per institutional availability. May start 7 days/week if available. Prefer morning infusions due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).
- **Approximate Chair time**
  - 255 minutes.
- **Labs During Treatment**
  - CBC with diff, CMP, uric acid, and phosphorus prior to treatment.
- **Additional RN Assessments**
  - According to institution policy.
- **APP and/or Clinical PharmD Assessments**
  - Perform patient assessment in infusion center prior to chemotherapy administration. Assess for toxicities (n/v, neuropathy, signs of volume overload or other signs of veno-occlusive disease, constipation), transfusion needs and signs of tumor lysis syndrome. Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.
- **Additional Staff Needed**
  - Dedicated APP.
- **In-Home Delivery Possible**
  - No.

### Post-Treatment

**Afterhours Troubleshooting**
- Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.
- **Labs Post-Chemo**
  - Individualized per patient – may range from daily to every 2-3 days after each gemtuzumab treatment. Twice weekly clinic visits for transfusion support, monitoring of possible hepatotoxicity and other toxicities.
- **Chemo Clearance Follow-up Considerations**
  - Chemo clearance visit in clinic 1-3 days prior to each cycle.
- **Indications/Diagnosis Code**
  - Newly diagnosed or relapsed/refractory Acute Myeloid Leukemia C92.02.
High-Dose Methotrexate

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

Pre-Work

**Suitability for Outpatient Administration**
- Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution.
- Patient is not currently taking any interacting medications. Patient must be able to be compliant with oral medications and oral hydration and must bring prescribed supportive care medications to infusion.

**Need for Caregiver**
- Not required.

**Social Work Consult to Aid with Lodging/Transportation**
- Required if patient needs assistance with local lodging and/or transportation.

**Patient Education Provided by Pharmacist**
- Required; see attached patient education example.

**Specific Line (port vs PICC) Needed**
- Central line per institutional policy.

**Financial Clearance**
- Oral leucovorin and sodium bicarbonate tablet prescriptions filled/approved by insurance.

**Labs for Chemo Clearance**
- CMP, CBC with diff, urine pH.

Treatment

**Infusion Center Accommodations**
- Start dates per institutional availability. May start 7 days/week if available. Must be open long hours to accommodate IV hydration with sodium bicarbonate/acetate 3-5 L/day and 4-hour methotrexate infusion on Day 1.

**Approximate Chair time**
- 600 minutes.

**Labs During Treatment**
- Urine pH >8 to start MTX infusion and urine pH every 2-3 hours while patient in infusion. CMP, Mag daily, 24 and 48 hour MTX levels and additional levels if indicated.

**Additional RN Assessments**
- Must record urine pH and I/Os, urine pH every 2-3 hours while patient in infusion center. Confirm leucovorin and sodium bicarb tablet prescriptions have been sent/filled.

**APP and/or Clinical PharmD Assessments**
- Assess methotrexate levels: 24 hour MTX level must be <10 microM, 48 hour MTX level must be <1 microM. MTX level must be <0.05 microM prior to patient discharge home on Day 3. APP/PharmD to adjust oral sodium bicarb tablet dosing to maintain urine pH >8 while on treatment; Confirm compliance with sodium bicarb and leucovorin. Patient instructed to bring to all infusion appointments; pharmacy will dispense oral supportive care medications if patient does not bring them in.

**Miscellaneous**
- Lab must be able to run MTX levels in-house with turn-around time of <1-2 hours; outpatient delivery not compatible with send out levels. Elevated methotrexate levels +/- AKI requiring admission managed per institutional guidelines. Replace electrolytes per institutional guidelines.

**Additional Staff Needed**
- Dedicated APP +/- PharmD for assessment of MTX levels, leucovorin dosing, sodium bicarb tablet dosing.

**In-Home Delivery Possible**
- No.

Post-Treatment

**Afterhours Troubleshooting**
- Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

**Labs Post-Chemo**
- Per institutional guidelines based on disease state.

**Chemo Clearance Follow-up Considerations**
- Patient to be seen in clinic with labs 1-7 days prior to cycle starting. Drug-drug interactions reviewed in anticipation of subsequent cycle.

**Indications/Diagnosis Code**
- Sarcoma C49.9, Primary CNS Lymphoma C85.89, High Risk Diffuse Large B-Cell Lymphoma (in addition to R-CHOP) C83.3.
The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

**Pre-Work**

**Suitability for Outpatient Administration**
Provided under general infusion schedule. Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Patient instructed to bring eye drops to infusion center appointments to confirm compliance.

**Need for Caregiver**
Not required.

**Social Work Consult to Aid with Lodging/Transportation**
Required if patient needs assistance with local lodging and/or transportation.

**Patient Education Provided by Pharmacist**
Required; see attached patient education example.

**Specific Line (port vs PICC) Needed**
Central Line per institutional policy

**Financial Clearance**
Not required.

**Labs for Chemo Clearance**
CMP, CBC with diff.

**Treatment**

**Infusion Center Accommodations**
Start dates per institutional availability. May start 7 days/week if available. Administered during off peak hours (~0700 and 1730; every 12 hours; may be administered every 10 hours per institutional policy)

**Approximate Chair time**
120 minutes in AM (~0700) and 120 minutes in PM (~1730) on days of treatment.

**Labs During Treatment**
None.

**Additional RN Assessments**
Neurotoxicity score prior to each dose of cytarabine. Ensure that patient is using eye drops as directed. According to institutional policy.

**APP and/or Clinical PharmD Assessments**
Not required during therapy.

**Miscellaneous**
Patient provided prescription for eye gtts and instructed to bring to all infusion appointments; pharmacy will dispense eye gtts if patient does not bring them in.

**Additional Staff Needed**
None.

**In-Home Delivery Possible**
Yes; see known variability.

**Post-Treatment**

**Afterhours Troubleshooting**
Provide standard afterhours procedures of institution.

**Labs Post-Chemo**
Patient specific: Clinic appointment once/twice weekly per institutional standard. Can be with local oncology team. Patient may be provided growth-factor support and started on neutropenic precautions per institutional standard.

**Chemo Clearance Follow-up Considerations**
Chemo clearance visit with labs 1-7 days prior to cycle.

**Indications/Diagnosis Code**
Acute Myeloid Leukemia C92.0.

**Known Variability:** Second dose may be administered at home by RN who also performs neurotoxicity checks. Cytarabine to be given on Days 1, 2, 3 or Days 1, 3, and 5 per institutional standards and NCCN guidelines. May see patients back 2-3 times per week for transfusion support and to initiate neutropenic precautions/prophylaxis when using ANC drops.
HyperCVAD Arm-A

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

Pre-Work

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Not Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Not required.

Labs for Chemo Clearance
CMP, CBC with diff.
MUGA/ECHO prior to Cycle 1

Treatment

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Administered during off peak hours (~0700 and 1730) due to cyclophosphamide administration (every 12 hours Days 1-3; may be administered every 10 hours per institutional policy).

Approximate Chair time
Day 1-3: 120 minutes (AM), 75 minutes (PM).
Day 4: 55 minutes.
Day 11: 25 minutes.

Labs During Treatment
Days 2-4: Urine analysis prior to chemotherapy administration.
Day 11: CMP prior to vincristine.

Additional RN Assessments
Mesna bag change. Weights checked Days 1-3.
According to institutional policy.

APP and/or Clinical PharmD Assessments
Perform patient assessment daily (Days 1-4) in infusion center to assess for toxicities. APP may see patient in clinic prior to Day 11 vincristine for chemo clearance.
Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.

Miscellaneous
Patient sent home with Mesna pump starting on Day 1 with disconnect on Day 4. High risk for febrile neutropenia: growth factor support per institutional policy and individual insurance. Pump battery changed every 3-4 days per institution policy. If intrathecal chemotherapy is required, prefer day 1 to minimize complications with completion of chemo bags.

Additional Staff Needed: Dedicated APP +/- PharmD

Post-Treatment

Afterhours Troubleshooting
Provide phone number for pump specific issues and on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

Labs Post-Chemo
Twice weekly clinic visits to assess for cytopenias, neutropenia, aid with dose adjustment for subsequent cycles and monitor for transfusion needs.

Chemo Clearance Follow-up Considerations
Chemo clearance visit in clinic 1-7 days prior to subsequent cycle.

Indications/Diagnosis Code
Acute Lymphoblastic Leukemia C91.00, Burkitts Lymphoma C83.7, Aggressive T-Cell Lymphomas C84.48.

Known Variability: First rituximab infusion is given on day 5 over slow rate. If no infusion reactions experienced with prior rituximab cycle, a rapid infusion over 90 minutes may be used on day 4 or 5 per institutional availability. Subcutaneous Rituximab Hyaluronidase may be substituted for rituximab after patients receive first full dose of rituximab by intravenous infusion.
ICE +/- Rituximab

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**Pre-Work**

**Suitability for Outpatient Administration**
Provided under general infusion schedule. Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution.

**Need for Caregiver**
Not required.

**Social Work Consult to Aid with Lodging/Transportation**
Required if patient needs assistance with local lodging and/or transportation.

**Patient Education Provided by Pharmacist**
Required; see attached patient education example.

**Specific Line (port vs PICC) Needed**
Central line per institutional policy.

**Financial Clearance**
Not required.

**Labs for Chemo Clearance**
CMP, CBC with diff.

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**Treatment**

**Infusion Center Accommodations**
Start dates per institutional availability. May start 7 days/week if available.

**Approximate Chair time**
- Day 1: 300 minutes.
- Days 2-3: 240 minutes.
- Day 4: Variable (either short time for pump disconnect or additional time for rituximab).

**Labs During Treatment**
- UA prior to chemotherapy Days 2-4.
- CMP + Mag on Days 2-3.

**Additional RN Assessments**
- Neuro assessment, mesna bag change, and weight monitored Days 1-3. According to institutional policy.

**APP and/or Clinical PharmD Assessments**
Not required during treatment cycle.

**Miscellaneous**
- Patient sent home with Mesna pump starting on Day 1 with disconnect on Day 4. High risk for febrile neutropenia: growth factor support per institutional policy and individual insurance. Pump battery changed every 3-4 days per institution policy.

**Additional Staff Needed**
None.

**In-Home Delivery Possible**
No.

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**Post-Treatment**

**Afterhours Troubleshooting**
Provide phone number for pump specific issues. Provide standard afterhours procedures of institution.

**Labs Post-Chemo**
Patient specific: Clinic appointment once/twice weekly. Can be with team near patient home.

**Chemotherapy Clearance Follow-up Considerations**
Chemotherapy clearance visit with labs 1-7 days prior to cycle starting.

**Indications/Diagnosis Code**
- Relapsed/Refractory Hodgkins Lymphoma C81.90,
- Relapsed/Refractory Aggressive B and T Cell Non-Hodgkins Lymphomas C85.80.

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**Known Variability:** First rituximab infusion is given at slow rate. If no infusion reactions experienced with prior rituximab cycle, a rapid infusion may be used per institutional availability. Day of rituximab infusion per institutional policy with Day 1, 4, 5 generally acceptable dates depending on duration of infusion. Subcutaneous Rituximab Hyaluronidase may be substituted for rituximab after patients receive first full dose of rituximab by intravenous infusion.
Inotuzumab

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Required prior to outpatient administration.

Labs for Chemo Clearance
CMP, CBC with diff., PT, APTT

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer morning infusions due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).

Approximate Chair time
165 minutes.

Labs During Treatment
CBC with diff, CMP, uric acid, and phosphorus.

Additional RN Assessments
According to institution policy.

APP and/or Clinical PharmD Assessments
Perform patient assessment in infusion center prior to chemotherapy administration. Assess for toxicities (n/v, neuropathy, signs of volume overload or other signs of veno-occlusive disease, constipation), transfusion needs and signs of tumor lysis syndrome. Ensure appropriate prophylactic medications have been prescribed and patient understands treatment plan.

Additional Staff Needed
Dedicated APP.

In-Home Delivery Possible
No.

Afterhours Troubleshooting
Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

Labs Post-Chemo
Individualized per patient – may range from daily to every 2-3 days after each inotuzumab treatment. Twice weekly clinic visits for transfusion support, monitoring of possible hepatotoxicity and other toxicities.

Chemo Clearance Follow-up Considerations
Chemo clearance visit in clinic 1-3 days prior to each cycle. Clearance visit in clinic prior to day 8 +/- 15 per institutional policy.

Indications/Diagnosis Code
Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia C91.00.
MiniCVD Arm A + Inotuzumab

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**Pre-Work**

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Preferred

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example

Specific Line (port vs PICC) Needed
Central line per institutional policy.

Financial Clearance
Required prior to outpatient administration.

Labs for Chemo Clearance
CMP, CBC with diff.

**Treatment**

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer morning infusions due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).

Approximate Chair time
Day 1: 120 min AM and 75 min PM
Day 2: 255 min AM and 75 min PM
Day 3: 120 min AM and 75 min PM
Day 4: 30 min
Day 8: 180 min

Labs During Treatment
CBC with diff, CMP, LDH, Urinalysis with micro

Additional RN Assessments
According to institution policy
Monitor for infusion reactions for an hour after inotuzumab

APP and/or Clinical PharmD Assessments
Assessed on days 1-3 AM, and on Day 8
Monitor for signs and symptoms of VOD (weight gain, lower leg edema, abdominal pain or bloating, liver lab abnormalities)

Miscellaneous
Patient sent home with Mesna pump starting on Day 1 with disconnect on Day 4. High risk for febrile neutropenia: growth factor support per institutional policy and individual insurance. Pump battery changed every 3-4 days per institution policy. If intrathecal chemotherapy is required, prefer day 1 to minimize complications with completion of chemo bags.

Additional Staff Needed:
Dedicated APP + PharmD

In-Home Delivery Possible: No

**Post-Treatment**

Afterhours Troubleshooting
Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER. Inpatient bed available.

Labs Post-Chemo
Individualized per patient – may range from daily to every 2-3 days a week.

Chemo Clearance Follow-up Considerations
Chemo clearance visit in clinic 1-3 days prior to each cycle

Indications/Diagnosis Code
Relapsed/refractory Acute lymphoblastic leukemia

Known Variability: First rituximab infusion is given on day 5 over slow rate. If no infusion reactions experienced with prior rituximab cycle, a rapid infusion over 90 minutes may be used on day 4 or 5 per institutional availability. Subcutaneous Rituximab Hyaluronidase may be substituted for rituximab after patients receive first full dose of rituximab by intravenous infusion.
Moxetumomab

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

**Pre-Work**

Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Not Required.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line preferred.

Financial Clearance
Required prior to outpatient administration.

Labs for Chemo Clearance
CMP, CBC with diff, Uric Acid.

**Treatment**

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer morning infusions due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).

Approximate Chair time
285 minutes

Labs During Treatment
CBC/diff, Uric Acid, CMP Days 1, 3, 5 + Day 8.

Additional RN Assessments
According to institution policy.

APP and/or Clinical PharmD Assessments
Assessed Day 1-5. If there are lab abnormalities or symptoms that require close monitoring, additional assessment visits may be scheduled for up to day 10.

Two possible side effects include capillary leak syndrome (CLS) and hemolytic uremic syndrome (HUS). Signs and symptoms of CLS: weight gain (> 5.5 lbs from day 1), low blood pressure, dizziness. Signs and symptoms of HUS: decreased urination, blood in urine or stool, unexplained bruising or bleeding, extreme fatigue.

Additional Staff Needed
Dedicated APP +/- PharmD.

In-Home Delivery Possible
No.

**Post-Treatment**

Afterhours Troubleshooting
Provide phone number for on-call physician who can troubleshoot issues or refer to hospital ER.

Labs Post-Chemo
Individualized per patient – may range from daily to every 2-3 days after each treatment.

Chemo Clearance Follow-up Considerations
Chemo clearance visit in clinic 1-3 days prior to each cycle.

Indications/Diagnosis Code
Hairy Cell Leukemia
Suitability for Outpatient Administration
Patient is reliable, compliant and has suitable transportation. Housing within 1 hour of institution. Not at high risk for TLS as defined per institutional standard.

Need for Caregiver
Preferred.

Social Work Consult to Aid with Lodging/Transportation
Required if patient needs assistance with local lodging and/or transportation.

Patient Education Provided by Pharmacist
Required; see attached patient education example.

Specific Line (port vs PICC) Needed
Central line preferred.

Financial Clearance
Required prior to Cycle 1.

Labs for Chemo Clearance
CMP, CBC with diff

Infusion Center Accommodations
Start dates per institutional availability. May start 7 days/week if available. Prefer morning infusions due to possible need for additional interventions (i.e. IVFs, transfusions, electrolytes).

Approximate Chair time
270 minutes.

Labs During Treatment
CBC with diff, CMP

Additional RN Assessments
According to institution policy. Check daily weight, temperature and blood pressure prior to treatment. Monitor for infusion reactions up to 4 hours after infusion.

APP and/or Clinical PharmD Assessments
Perform patient assessment in infusion center prior to chemotherapy administration. Intervention required and therapy should be held if; Heart rate ≥130 bpm or ≤40 bpm, Systolic blood pressure ≥160 mm Hg or ≤80 mm Hg, Serum albumin <3.5 g/dL or serum albumin reduced by ≥0.5 g/dL from the value measured prior to Day 1 of current cycle, Pre-dose body weight increased by ≥1.5 kg over the previous day's pre-dose weight, Body temperature is > 100.4 °F, Edema, fluid overload, and/or hypotension.

Additional Staff Needed
Dedicated APP + PharmD.

In-Home Delivery Possible
No.

Known Variability: Cycle 1 administered inpatient per package insert; Missed doses may be administered up to Day 10 per package insert.
Sample Patient Education Documents
Appendix

Patient Education: Blinatumomab Cycle #1

Schedule:
1. You will be scheduled for a PICC line placement for this chemotherapy.
2. You will be admitted to the hospital for at least the first 9 days of chemotherapy.
3. You will receive blinatumomab via an ambulatory pump that will deliver it continuously while in the hospital or at home.
4. After being discharged from the hospital, you will receive the remaining doses in the Infusion Center. Arrive at the Infusion Center around 8am on each day of therapy. Please be on time so we can keep your treatment plan on schedule.
   - Your pump will be checked and refilled by the Infusion Center staff.
   - A nurse will complete a neuro assessment each day prior to changing the bag.
5. You will be required to have labs within 7 days prior to starting each cycle.
6. After Day 29, you will be required to have labs checked at least once weekly with PICC line dressing changes.

Prescriptions:
1. You may continue on antibiotics after discharge from the hospital.
   - Acyclovir 800mg twice daily (continue for entire duration of treatment)
   - Ciprofloxacin 500mg twice daily
   - Δ +/- Sulfamethoxazole-trimethoprim single strength (Bactrim) 1 tablet daily
   - Other ____________________________

2. Depending on your disease, you may receive a prescription for an oral chemotherapy.
   - ____________________________ [drug/dose]
   - Antacids can decrease absorption of the oral chemotherapy and should be avoided. Avoid the following antacids:
     Protonix ( pantoprazole), Prilosec ( omeprazole), Zantac ( ranitidine), Pepcid ( famotidine)

3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to ______ times daily</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 4 times daily</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 3 times daily</td>
</tr>
</tbody>
</table>

   - Prescription(s) for ____________________________ were sent to ______________________ pharmacy.
## Appendix

### Calendar: Blinatumomab Cycle #1

Abbreviated regimen overview:
- Blinatumomab is administered via continuous infusion for 4 weeks (days 1 – 28), followed by two-weeks off.
- Possible side effects: Fatigue, fever, rash, neurotoxicity (severe headache, confusion), nausea/vomiting, constipation, seizure, liver function test abnormalities, low potassium.

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Inpatient</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Bag #1</strong></td>
<td></td>
<td><strong>Bag #2</strong></td>
<td></td>
<td><strong>Bag #3</strong></td>
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<tr>
<td><strong>Day 8</strong></td>
<td><strong>Day 9</strong></td>
<td><strong>Day 10</strong></td>
<td><strong>Day 11</strong></td>
<td><strong>Day 12</strong></td>
<td><strong>Day 13</strong></td>
<td><strong>Day 14</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Inpatient</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Bag #4</strong></td>
<td><strong>Bag #5</strong></td>
<td><strong>Bag #6</strong></td>
<td><strong>Bag #7</strong></td>
</tr>
<tr>
<td><strong>Day 15</strong></td>
<td><strong>Day 16</strong></td>
<td><strong>Day 17</strong></td>
<td><strong>Day 18</strong></td>
<td><strong>Day 19</strong></td>
<td><strong>Day 20</strong></td>
<td><strong>Day 21</strong></td>
</tr>
<tr>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
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<tr>
<td><strong>Bag #8</strong></td>
<td><strong>Bag #9</strong></td>
<td><strong>Bag #10</strong></td>
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<tr>
<td><strong>Day 22</strong></td>
<td><strong>Day 23</strong></td>
<td><strong>Day 24</strong></td>
<td><strong>Day 25</strong></td>
<td><strong>Day 26</strong></td>
<td><strong>Day 27</strong></td>
<td><strong>Day 28</strong></td>
</tr>
<tr>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
<td><strong>Clinic visit</strong></td>
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<tr>
<td><strong>Bag #11</strong></td>
<td><strong>Bag #12</strong></td>
<td><strong>Bag #13</strong></td>
<td><strong>Bag #14</strong></td>
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<tr>
<td>Day 29</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Pump disconnect in Infusion Center</strong></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Do not drive or operate heavy machinery. Please let your provider know if you develop any of the side effects listed above – especially fever, neurologic symptoms or have difficulties with the pump. Clinic can be reached at ________________________.

Ambulatory Home Pump problems: Contact ________________________.

20
Patient Education: Cytarabine/Daunorubicin Liposome Induction

Schedule:
1. You will be required to have labs drawn within 7 days prior to starting chemotherapy.
   - You will also receive a central line.
   - Heart function is checked before starting chemotherapy.
   - Chemotherapy starts on Day 1.
2. Day 1__________ [date], Day 3__________[date], and Day 5__________ [date]
   - Arrive at the Infusion Center in the morning to have labs checked.
   - About 2 hours later, you will receive pre-medications, followed by cytarabine/daunorubicin liposome (chemotherapy). You might receive extra IV fluids, transfusions, or electrolytes if needed.
   - A provider will come see you after your labs are checked and before you receive chemotherapy.
   - You should drink at least 2 liters of fluid daily.
   - Avoid over eating or drinking products with high potassium (examples: Gatorade®, bananas, spinach).
3. Depending on your disease, you might be assessed on Day 2 and Day 4.
   - You may receive labs and have a clinic or Infusion Center appointment on Day 2 and Day 4.
   - You may receive extra IV fluids, transfusions, or electrolytes if needed.
4. Day 6
   - You will receive a phone call from the admitting office when an inpatient bed is available. If you do not receive a call by mid-morning, please call ________________.
   - Please plan to be hospitalized for 25 – 50 days (average is 30 days).
5. Please plan to have a repeat bone marrow biopsy near Day 14 to check your response to treatment.
6. In the future, you may receive additional cycles of this chemotherapy in the outpatient setting.

Prescriptions:
1. Prescriptions were sent to ________________ pharmacy.
   - Allopurinol 300mg [one or twice] daily
2. You might be given antibiotics to help prevent infection during chemotherapy.
   - Acyclovir 800mg twice daily (continue for entire duration of treatment)
   - Ciprofloxacin 500mg twice daily
   - Other
3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>∆</td>
<td>∆</td>
<td>Take 1 tablet as needed up to 4 times daily</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>∆</td>
<td>∆</td>
<td>Take 1 tablet as needed up to 3 times daily</td>
</tr>
</tbody>
</table>

   - Prescription(s) for ________________ were sent to ________________ pharmacy.
4. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, MiraLax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
Abbreviated regimen overview

*Possible Side effects:
- Low blood counts, infection, rash, mouth sores, red/orange-tinged urine, heart failure, increased risk of serious bleeding.

<table>
<thead>
<tr>
<th>Days</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cytarabine/</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Admitted to hospital until</td>
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</tr>
<tr>
<td></td>
<td>daunorubicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>blood counts recover</td>
<td></td>
</tr>
<tr>
<td></td>
<td>daunorubicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>liposome</td>
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<td></td>
<td>Once via IV</td>
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<td></td>
<td>Day 8</td>
<td>Day 9</td>
<td>Day 10</td>
<td>Day 11</td>
<td>Day 12</td>
<td>Day 13</td>
<td>Day 14</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Bone Marrow Biopsy</td>
</tr>
</tbody>
</table>

- If you develop fever or chills, you may be admitted before Day 6. It is important to let your provider know if you develop fever or other signs of infection.
- *Please let your provider know if you develop any of the side effects listed above.
- Clinic can be reached at _________________________.
Appendix

Patient Education: Dose Adjusted EPOCH

Schedule:
1. On Days 1 – 4, you will receive your chemotherapy via an ambulatory pump that will deliver doxorubicin, etoposide and vincristine (in one bag) over 24-hours while at home. Please arrive to the Infusion Center on time so we can prevent interruption of treatment.
   - This pump will be checked and refilled by the Infusion Center staff during the first 4 days of each cycle.
   - If you think the bag will finish before your appointment, come straight to the Infusion Center (during Infusion Center hours) or call the on-call MD (after hours).
     - Infusion Center hours: ________________________________
     - On-call MD: ________________________________

2. On Day 5 [date], most patients receive an infusion of cyclophosphamide in the Infusion Center.
   - You will also have your ambulatory pump disconnected this day.

3. Depending on your disease, you may also receive rituximab [date]
   - The first rituximab infusion will be infused over 6-8 hours on Day 6.
   - If you tolerate rituximab well, it can be given over a shorter time on Day 5 starting with Cycle 2.

4. You will receive a growth factor that boosts your white blood cells following chemotherapy. This is given as an injection underneath the skin (SQ) beginning 24 – 72 hours after your Day 5 chemotherapy.
   - Many patients receive the pegfilgrastim (Neulasta) On-Body-Injector (Neulasta OBI), which is applied on the same day as chemotherapy on Day 5.
     - Approximately 27 hours later, the OBI will deliver the medication over 45 minutes.
     - Dispose of the OBI in a sharps container (provided by manufacturer).

5. Depending on your disease, you may also receive a lumbar puncture(s) for intrathecal chemotherapy.
   - [dates]

6. You will be required to have labs within 7 days prior to starting each cycle.
   - Labs will be drawn twice weekly for 2 weeks after completion of your chemotherapy. The results of these labs may affect the dosing of future chemotherapy cycles.

Prescriptions:
1. You will receive one dose of prednisone in the Infusion Center prior to chemotherapy on Days 1 – 5.
2. You may be given antibiotics to help prevent infection. Start taking on Day 6 [__________].
   - Acyclovir 800mg twice daily (continue for entire duration of treatment)
   - Sulfamethoxazole-trimethoprim single strength (Bactrim) 1 tablet daily
   - Other [__________]

3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>∆</td>
<td>∆</td>
<td>Take 1 tablet up to ______ times daily. Do not take Days 1-7</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>∆</td>
<td>∆</td>
<td>Take 1 tablet up to 4 times daily</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>∆</td>
<td>∆</td>
<td>Take 1 tablet up to 3 times daily</td>
</tr>
</tbody>
</table>

   - Prescription(s) for ______________________ were sent to ______________________ pharmacy.

4. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, MiraLax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
### Calendar: Dose Adjusted EPOCH

**Abbreviated regimen overview**

<table>
<thead>
<tr>
<th></th>
<th>*Possible Side Effects</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prednisone</strong></td>
<td>Trouble sleeping, mood changes, increased blood sugar or blood pressure</td>
<td></td>
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</tr>
<tr>
<td><strong>Doxorubicin</strong> (Adriamycin)</td>
<td>Hair loss, nausea, vomiting, red urine, mouth sores, heart failure</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Etoposide</strong> (Toposar)</td>
<td>Hair loss, mouth sores, nausea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pump disconnect</td>
</tr>
<tr>
<td><strong>Vincristine</strong> (Oncovin)</td>
<td>Numbness, tingling, nerve pain, constipation, weakness</td>
<td>via continuous infusion</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cyclophosphamide</strong> (Cytoxan)</td>
<td>Hair loss, nausea, vomiting, blood in urine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Once via IV</td>
</tr>
<tr>
<td><strong>Pegfilgrastim</strong> (Neulasta)</td>
<td>Bone pain, fever</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rituximab</strong> (Rituxan)</td>
<td>Infusion-type reactions, fever, rigors and/or chills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intrathecal Chemotherapy</strong></td>
<td>Headache, nausea, vomiting</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please let your provider know if you develop any of the side effects listed above. Clinic can be reached at _________________.  
Ambulatory Home Pump problems: Contact _________________.

---
Appendix

Patient Education: Gemtuzumab

Schedule:
1. You will be required to have labs drawn within 7 days prior to starting chemotherapy.
2. Day 1 [date], Day 4 [date], and Day 7 [date]
   - Arrive at the Infusion Center in the morning to have labs checked.
   - After you receive pre-medications and chemotherapy, you will be monitored for infusion-reactions for at least one-hour in the Infusion Center.
   - Possible symptoms include fever, chills, and/or rash.
3. A possible side effect of this chemotherapy is veno-occlusive disease (VOD). It is important to watch for signs and symptoms of VOD while at home.
   - Signs and symptoms: weight gain, lower leg edema, abdominal pain, abdominal bloating, liver lab abnormalities
4. Avoid over-eating or drinking products with high potassium (examples: Gatorade®, bananas, spinach).
5. You will be required to have daily labs and provider visits after receiving this chemotherapy. The frequency of visits may be reduced based on your symptoms and laboratory values.

Prescriptions:
1. Prescriptions were sent to ______________________pharmacy.
   - Allopurinol 300mg [one or twice] daily

2. You may be given antibiotics to help prevent infection during chemotherapy.
   - Acyclovir 800mg twice daily (continue for entire duration of treatment)
   - Ciprofloxacin 500mg twice daily
   - Other ____________________________

3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to ______ times daily</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to 4 times daily</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to 3 times daily</td>
</tr>
</tbody>
</table>

- Prescription(s) for _________________________ were sent to ______________________ pharmacy.
Abbreviated regimen overview

*Possible side effects:
- Fatigue, nausea, vomiting, infection, rash, headache, infusion-reaction (fever, chills, rash), mucositis (mouth sores), edema, abdominal pain, abdominal bloating, liver damage, veno-occlusive disease (VOD), and low blood counts.

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once via IV</td>
<td></td>
<td>Once via IV</td>
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<td>Once via IV</td>
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<tr>
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*Please let your provider know if you develop any of the side effects listed above.

Clinic can be reached at____________________.
Appendix

Patient Education: High Dose Methotrexate

How is this regimen given?

• Methotrexate will be administered into a vein (IV) over 4 hours on Days 1 and 8 of your chemotherapy cycle.

• Your time in infusion will be longer than the drug administration times.

The night before chemotherapy:
1. You will take sodium bicarbonate by mouth (5 tablets = dose of 3250mg) twice daily.

On Days 1 and 8:
1. IV fluids will be given over at least 3 hours
2. Methotrexate will be given by IV over 4 hours
3. You will take sodium bicarbonate by mouth twice daily

On Days 2 and 9:
1. IV fluids will be given over at least 3 hours
2. Leucovorin will be given by IV over 15 minutes
3. You will take leucovorin by mouth every 6 hours starting 6 hours after the IV dose of leucovorin
4. You will take sodium bicarbonate by mouth twice daily

On Days 3 and 10:
1. IV fluids will be given over at least 3 hours
2. You will take leucovorin by mouth every 6 hours
3. You will take sodium bicarbonate by mouth twice daily

Are there other medications I will receive with this regimen?
Yes. You will receive other medications to help prevent possible side effects of the chemotherapy or help the chemotherapy to work better.

1. Medicines to prevent nausea and treat nausea will be available as needed.
2. Additional sodium bicarbonate will be given as needed (if urine pH is less than 8).
3. Leucovorin is a vitamin that will be used with this regimen to decrease side effects. It is important to take all of this medication as directed when you are asked to take tablets at home.
What medications should I avoid with this regimen?

1. Non-steroidal anti-inflammatory drugs (NSAIDs) should not be taken with this medication. Some examples of NSAIDs include: Ibuprofen (Motrin/Advil), Naproxen (Aleve), Meloxicam (Mobic), Celecoxib (Celebrex), and Aspirin.

2. Proton Pump Inhibitors (PPIs). Some examples of PPIs include: Omeprazole (Prilosec), Pantoprazole (Protonix), Lansoprazole (Prevacid), and Esomeprazole (Nexium).

3. Some antibiotics including penicillins should be avoided. Some examples include Amoxicillin, Augmentin, and Penicillin (G, VK, others). Ciprofloxacin and levofloxacin antibiotics should be avoided. Bactrim should be avoided.

What side effects can occur with this regimen?

This information does not cover all possible side effects, but highlights the side effects seen most frequently. You know what is “normal” for your body best—if you are experiencing a change in one of your symptoms not listed here, please contact your clinic with questions.

- Decreased blood cell counts (Lack of enough red blood cells, platelets, and white blood cells)
- Nausea or vomiting
- Mucositis (Irritation or sores in the lining of the mouth, throat or lips)
- Rash
- Diarrhea
- Hepatic dysfunction (Liver not working normally)
- Kidney Dysfunction (Changes in kidney function)
- Alopecia (Hair loss)
- Photosensitivity (Increased skin sensitivity to sunlight)
Patient Education: High-Dose or Intermediate-Dose Cytarabine Consolidation

Schedule:
1. Arrive at the infusion center at **7:00 AM** each day. Please be on time in order to keep treatment on schedule.
   - Before starting pre-medications, you will be assessed by nursing staff. This will include neuro-checks.
   - Premedication will begin around 7:30 AM and the first dose of chemotherapy will begin at 8:00 AM.
2. Return to the infusion center around **5:00 PM** on Days 1, 3 and 5 to be assessed by nursing staff.
   - You will again receive neuro-checks, then receive pre-medications.
   - After being assessed, you will receive the next dose of chemotherapy.
3. On Day 7 [date], you will start receiving a growth factor called Zarxio or Neupogen (filgrastim) that boosts your white blood cells following chemotherapy.
   - It is given as an injection underneath the skin (SQ) for up to 14 days at [infusion center/home/local oncologist]
4. You will be required to have labs drawn within 7 days of starting each cycle and at least twice weekly after each cycle.

Prescriptions:
1. You will be given **corticosteroid eye drops** to help prevent eye irritation.
   - Instill 2 drops in each eye every 6 hours starting Day 1 (prior to getting first chemotherapy).
   - Continue through Day 6 [date]
   - **Bring eye drops with you to each infusion appointment.**
   - **Do not wear eye contacts Days 1 – 6**
2. You will be given antibiotic(s) to help prevent infection. Start taking on Day 6 [date]
   - Fluconazole 200mg once daily for 10-14 days
   - One of the following antibiotics for 10-14 days
     - Ciprofloxacin 500mg twice daily OR
     - Sulfamethoxazole-trimethoprim double strength (Bactrim DS) 1 tablet twice daily OR
     - Cefdinir 300mg twice daily for 10-14 days
3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>☐</td>
<td>☐</td>
<td>Take 1 tablet up to ___ times daily. Do not take Days 1-6.</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>☐</td>
<td>☐</td>
<td>Take 1 tablet up to 4 times daily.</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>☐</td>
<td>☐</td>
<td>Take 1 tablet up to 3 times daily.</td>
</tr>
</tbody>
</table>

- Prescription(s) for ______________ were sent to ______________ pharmacy.

4. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, MiraLax, Colace [docusate]) are available over-the-counter (OTC) at your local pharmacy.
Calendar: High-Dose or Intermediate-Dose Cytarabine Consolidation

Abbreviated regimen overview  Possible side effects*:

- **Cytarabine**: Fatigue, nausea, vomiting, infection, rash, eye irritation, eye infection, neurotoxicity (slurred speech, difficulty writing or walking, tremors)
- **Filgrastim**: bone pain, fever

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twice daily via IV</td>
<td>Twice daily via IV</td>
<td>Twice daily via IV</td>
<td>Filgrastim once daily via SQ</td>
<td></td>
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<tr>
<td>Day 8</td>
<td>Day 9</td>
<td>Day 10</td>
<td>Day 11</td>
<td>Day 12</td>
<td>Day 13</td>
<td>Day 14</td>
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<tr>
<td>Filgrastim once daily via SQ</td>
<td>Filgrastim once daily via SQ</td>
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<td>Filgrastim once daily via SQ</td>
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<td>Day 15</td>
<td>Day 16</td>
<td>Day 17</td>
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<tr>
<td>Filgrastim once daily via SQ</td>
<td>Filgrastim once daily via SQ</td>
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<td>Filgrastim once daily via SQ</td>
<td>Filgrastim once daily via SQ</td>
<td>Filgrastim once daily via SQ</td>
<td></td>
</tr>
</tbody>
</table>

*Please let your provider know if you develop any of these symptoms or develop a fever of 100.4°F or higher. Clinic can be reached at ____________________________.
Patient Education: HyperCVAD Arm A

Schedule:
1. Arrive at the Infusion Center at 7:00 AM each day. Please be on time in order to keep treatment on schedule.
   - Premedication will begin around 7:30 AM and the first dose of chemotherapy will begin at 8:00 AM.
2. Return to the Infusion Center around 5:00 PM on Days 1 – 3 to be checked by nursing staff.
   - You should drink at least 2 liters of fluid daily. If you notice blood in your urine, please call us right away.
   - Urine samples will be drawn on days 2, 3, and 4 to monitor for adverse effects of the chemotherapy.
   - After being checked, you will receive the next dose of chemotherapy.
3. You will receive a pump that delivers Mesna over 24 hours while you are at home. This pump will be checked and refilled daily by the Infusion Center staff.
4. On Day 11________[date], you will receive vincristine and restart dexamethasone.
   - This may be given at Moffitt or at your local oncologist’s office. Please let your clinic team know the location where you prefer to receive these drugs.
5. Depending on your disease, you may also receive rituximab.________[date]
   - The first rituximab infusion will be given over 6-8 hours.
   - If you tolerate rituximab well, it can be given over a shorter time starting with Cycle 2.
6. You will receive a growth factor that boosts your white blood cells following chemotherapy.
   - **Option (1):** Pegfilgrastim (Neulasta) On-Body-Injector (Neulasta OBI), which is applied on the same day as chemotherapy on Day 4________. Approximately 27 hours later, the Neulasta OBI will deliver the medication over 45 minutes.
   - **Option (2):** Pegfilgrastim, which is given 24-72 hours after chemotherapy. You will receive this on____[date] at Moffitt’s Infusion Center/ home / local oncologist.
7. You may also receive a lumbar puncture(s) for intrathecal chemotherapy:________[dates]
8. You will be required to have labs drawn within 7 days of starting each cycle and twice weekly after each cycle.

Prescriptions:
1. Dexamethasone is part of this regimen. Take in the morning with food to avoid stomach upset.
   - Days 1-4: Take dexamethasone 40mg in the Infusion Center (Infusion Center will provide).
   - Days 11-14: Take dexamethasone 40mg (10 tabs)________[dates] (take own supply at home).
2. You will be given antibiotic(s) to help prevent infection.
   - Acyclovir 800mg twice daily
   - Ciprofloxacin 500mg twice daily for 10 days
   - Sulfamethoxazole-trimethoprim single strength (Bactrim) tablet daily. Do not take beyond________.
   - Other________
3. Depending on your disease, you may receive a prescription for an oral chemotherapy.
   - ______[drug/dose]
   - **Antacids** can decrease absorption of the oral chemotherapy and should be avoided. Avoid the following antacids: Protonix (pantoprazole), Prilosec (omeprazole), Zantac (ranitidine), Pepcid (famotidine).
4. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
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</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to_____times daily. Do not take Days 1-5.</td>
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<tr>
<td>Prochlorperazine (Compazine)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 4 times daily</td>
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<tr>
<td>Lorazepam (Ativan)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 3 times daily</td>
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</tbody>
</table>
   - Prescription(s) for________ were sent to________ pharmacy.
5. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, Miralax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
# Appendix

## Calendar: HyperCVAD Arm A

### Abbreviated regimen overview

<table>
<thead>
<tr>
<th>Drug/Procedure</th>
<th>Day 1</th>
<th>Day 2</th>
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<td><strong>Dexamethasone</strong> (Decadron)</td>
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<td>Trouble sleeping, mood changes, increased blood</td>
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<td>sugar or blood pressure</td>
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<td><strong>Mesna</strong> (Mesnex)</td>
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<td><em>Possible Side Effects</em></td>
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<td><strong>Cyclophosphamide</strong> (Cytoxan)</td>
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<tr>
<td>Hair loss, nausea, vomiting, blood in urine</td>
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<td><strong>Doxorubicin</strong> (Adriamycin)</td>
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<td>Hair loss, nausea, vomiting, red urine, mouth</td>
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<td>sores, heart failure</td>
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<td><strong>Vincristine</strong> (Oncovin)</td>
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<td>Numbness, tingling, nerve pain, constipation,</td>
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<td><strong>Pegfilgrastim</strong> (Neulasta)</td>
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<td>Bone pain, fever</td>
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<td><strong>Rituximab</strong> (Rituxan)</td>
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<td><em>Possible Side Effects</em></td>
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<td>Infusion-type reactions, fever, rigors and/or</td>
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<td><strong>Intrathecal Chemotherapy</strong></td>
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<td><em>Possible Side Effects</em></td>
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<tr>
<td>Headache, nausea, vomiting</td>
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<td><strong>Other</strong></td>
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</tr>
</tbody>
</table>

*Please let your provider know if you develop any of the side effects listed above. Clinic can be reached at ________________.*

Ambulatory Home Pump problems: Contact ________________.
Appendix

Patient Education: ICE +/- Rituximab

Schedule:
1. You will be required to have labs drawn within 7 days of starting each cycle
   • More labs will be checked on Days 2, 3, and 4 to monitor for side effects of chemotherapy
   • Labs will also be checked twice weekly after each cycle of chemotherapy
2. Days 2________ [date], 3________ [date] and 4________ [date]
   • Before starting pre-medications, you will be assessed by nursing staff. This will include neuro-checks.
   • You should drink at least 2 liters of fluid daily. If you notice blood in the urine, please call to let us know.
   • Urine samples will be drawn on Days 2, 3 and 4 to monitor for adverse effects of the chemotherapy.
   • After being assessed, you will receive the next dose of chemotherapy.
3. You will receive a pump that delivers Mesna over 24-hours while you are at home. This pump will be checked
   and refilled daily by the infusion center staff.
4. Depending on your disease, you may also receive rituximab________[date]
   • The first rituximab infusion will be infused over 6-8 hours.
   • If you tolerate rituximab well, it can be given over a shorter time starting with Cycle 2.
5. You will receive a growth factor that boosts your white blood cells following chemotherapy.
   ▪ **Option (1):** Neulasta On-Body-Injector (Neulasta OBI), which is applied on the same day as
     chemotherapy on Day 4________.
     • Approximately 27 hours later, the Neulasta OBI will deliver the medication over 45-minutes.
   ▪ **Option (2):** Neulasta, which is given 24-72 hours after chemotherapy.
     • You will receive this on__________[date] at [infusion center/home/local oncologist]

Prescriptions:
1. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td></td>
<td></td>
<td>Take 1 tablet up to ______ times daily. Do not take Days 1-4.</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td></td>
<td></td>
<td>Take 1 tablet up to 4 times daily.</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td></td>
<td></td>
<td>Take 1 tablet up to 3 times daily.</td>
</tr>
</tbody>
</table>

• Prescription(s) for__________were sent to__________pharmacy.

2. You may experience constipation during your treatment. For relief, stimulants and stool softeners
   (Senokot/Senna, MiraLax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
## Appendix

### Calendar: ICE +/- Rituximab

<table>
<thead>
<tr>
<th>Abbreviated regimen overview</th>
<th>Possible Side effects</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Etoposide</strong> (Toposar)</td>
<td>Hair loss, nausea, vomiting, fatigue, mouth sores</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Carboplatin</strong> (Carboplatin)</td>
<td>Fatigue, numbness or tingling in fingers/toes, allergic reaction, increased risk of bleeding, infection</td>
<td>Once via IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ifosfamide + Mesna</strong> (Ifex) + (Mesnex)</td>
<td>Hair loss, nausea, vomiting, blood in urine, confusion</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mesna</strong> (Mesnex)</td>
<td></td>
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<td></td>
<td></td>
<td>Continuous infusion</td>
<td></td>
</tr>
<tr>
<td><strong>Rituximab</strong> (Rituxan)</td>
<td>Infusion-type reactions, fever, rigors and/or chills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Once via IV (+/-)</td>
</tr>
<tr>
<td><strong>Pegfilgrastim</strong> (Neulasta)</td>
<td>Bone pain, fever</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Please let your provider know if you develop any of these symptoms or develop a fever of 100.4° F or higher. Clinic can be reached at_____________________________. Ambulatory Home Pump problems: Contact_____________________________.*
Appendix

Patient Education: Inotuzumab

Schedule:
1. You will be required to have labs drawn within 7 days prior to starting chemotherapy.
2. Day 1___________[date], Day 8___________[date], and Day 15___________[date].
   - Arrive at the Infusion Center in the morning to have labs checked.
   - After you receive pre-medications and chemotherapy, you will be monitored for infusion-reactions for at least one-hour in the Infusion Center.
   - Possible symptoms include fever, chills and/or rash.
3. A possible side effect of this chemotherapy is veno-occlusive disease (VOD). It is important to watch for signs and symptoms of VOD while at home.
   - Signs & symptoms: weight gain, lower leg edema, abdominal pain or bloating, liver lab abnormalities.
4. Avoid over-eating or drinking products with high potassium (examples: Gatorade®, bananas, spinach).
5. You will be required to have daily labs and provider visits after receiving this chemotherapy. The frequency of visits may be reduced based on your symptoms and laboratory values.
6. You will likely receive a bone marrow biopsy the week after your completion of Cycle 1.

Prescriptions:
1. Prescriptions were sent to________________________pharmacy.
   - Allopurinol 300mg [one or twice] daily
2. You might be given antibiotics to help prevent infection during chemotherapy.
   - Acyclovir 400 twice daily (continue for entire duration of treatment)
   - Ciprofloxacin 500mg twice daily
   - Other __________________________
3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ondansetron (Zofran)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to_____ times daily</td>
</tr>
<tr>
<td>Prochlorperazine (Compazine)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to 4 times daily</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet as needed up to 3 times daily</td>
</tr>
</tbody>
</table>

- Prescription(s) for________________________ were sent to________________________pharmacy.
Abbreviated regimen overview
The first cycle is a 21-day cycle. Future cycles might be extended to 28 day cycles.

*Possible side effects:
- Fatigue, nausea, vomiting, infection, infusion-reaction (fever, chills, rash), swelling, abdominal pain, abdominal bloating, liver damage, veno-occlusive disease (VOD), and low blood counts.

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once via IV</td>
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<tr>
<td>Day 8</td>
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<td>Day 10</td>
<td>Day 11</td>
<td>Day 12</td>
<td>Day 13</td>
<td>Day 14</td>
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<tr>
<td>Once via IV</td>
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<tr>
<td>Day 15</td>
<td>Day 16</td>
<td>Day 17</td>
<td>Day 18</td>
<td>Day 19</td>
<td>Day 20</td>
<td>Day 21</td>
</tr>
<tr>
<td>Once via IV</td>
<td></td>
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</tr>
</tbody>
</table>

- *Please let your provider know if you develop any of the side effects listed above.
- Clinic can be reached at_____________________.

Appendix

Calendar: Inotuzumab
Patient Education: Mini-CVD Arm A + Inotuzumab

Schedule:

1. Arrive at the Infusion Center at 7:00 AM each day. Please be on time in order to keep treatment on schedule.
   - Premedication will begin around 7:30 AM and the first dose of chemotherapy will begin at 8:00 AM.
   - On Day 2 __________[date], you also receive inotuzumab.
     - After you receive pre-medications and chemotherapy, you will be monitored for infusion-reactions for at least one-hour in the Infusion Center.
     - Possible symptoms include fever, chills and/or rash.
2. Return to the Infusion Center around 5:00 PM on Days 1 – 3 to be checked by nursing staff.
   - You should drink at least 2 liters of fluid daily. If you notice blood in your urine, please call us right away.
3. On Day 8 __________[date], you will receive vincristine and inotuzumab.
   - After you receive pre-medications and chemotherapy, you will be monitored for infusion-reactions for at least one-hour in the Infusion Center.
4. On Day 11________[date], you will restart dexamethasone. This will be a prescription that you take at home.
5. Depending on your disease, you may also receive rituximab.__________[date]
   - The first rituximab infusion will be given over 6-8 hours.
   - If you tolerate rituximab well, it can be given over a shorter time starting with Cycle 2.
6. A possible side effect of this chemotherapy is veno-occlusive disease (VOD). It is important to watch for signs and symptoms of VOD while at home.
   - Signs & symptoms: weight gain, lower leg edema, abdominal pain or bloating, liver lab abnormalities.
7. You will receive a growth factor that boosts your white blood cells following chemotherapy.
   - Option (1): Neulasta On-Body-Injector (Neulasta OB1), which is applied on the same day as chemotherapy on Day 3____. Approximately 27 hours later, the Neulasta OB1 will deliver the medication over 45 minutes.
   - Option (2): Neulasta, which is given 24-72 hours after chemotherapy. You will receive this on __________[date] at Moffitt’s Infusion Center/ home / local oncologist.
8. You may also receive a lumbar puncture(s) for intrathecal chemotherapy; __________[dates]
9. You will be required to have labs drawn within 7 days of starting each cycle and twice weekly after each cycle.

Prescriptions:

1. Dexamethasone is part of this regimen. Take in the morning with food to avoid stomach upset.
   - Days 1-3: Take dexamethasone 20mg in the Infusion Center (Infusion Center will provide).
   - Days 4, 11-14: Take dexamethasone 20mg (5 tabs) __________[dates] (take own supply at home).
2. You will be given antibiotic(s) to help prevent infection.
   - Acyclovir 800mg twice daily
   - Ciprofloxacin 500mg twice daily for 10 days
   - Sulfamethoxazole-trimethoprim single strength (Bactrim) 1 tablet daily. Do not take beyond ______.
   - Other __________
3. Depending on your disease, you may receive a prescription for an oral chemotherapy.
   - __________[drug/dose]
   - Antacids can decrease absorption of the oral chemotherapy and should be avoided. Avoid the following antacids: Protonix (pantoprazole), Prilosec (omeprazole), Zantac (ranitidine), Pepsid (famotidine).
4. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions – as needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zofran (ondansetron)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to _____ times daily. Do not take Days 1-5.</td>
</tr>
<tr>
<td>Compazine (prochlorperazine)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 4 times daily</td>
</tr>
<tr>
<td>Ativan (lorazepam)</td>
<td>Δ</td>
<td>Δ</td>
<td>Take 1 tablet up to 3 times daily</td>
</tr>
</tbody>
</table>

   - Prescription(s) for ________________were sent to __________________pharmacy.

5. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, MiraLax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
# Appendix

## Calendar: MiniCVD Arm-A + Inotuzumab

<table>
<thead>
<tr>
<th>Drug</th>
<th>Possible Side Effects</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 8</th>
<th>Day 11</th>
<th>Day 12</th>
<th>Day 13</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone (Decadron)</td>
<td>Trouble sleeping, mood changes, increased blood sugar or blood pressure</td>
<td></td>
<td></td>
<td></td>
<td>Once daily by mouth (given in Infusion Center)</td>
<td>Once daily by mouth with food (take at home)</td>
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<tr>
<td>Cyclophosphamide (Cytoxan)</td>
<td>Hair loss, nausea, vomiting, blood in urine</td>
<td></td>
<td></td>
<td></td>
<td>Twice daily via IV</td>
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</tr>
<tr>
<td>Mesna (Mesnex)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Continuous infusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inotuzumab ozogamicin (Besponsa)</td>
<td>Fatigue, infection, infusion-reaction, abdominal pain/bloating, liver damage, VOD, low blood counts</td>
<td>Once via IV</td>
<td></td>
<td></td>
<td>Once via IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vincristine (Oncovin)</td>
<td>Numbness, tingling, nerve pain, constipation, weakness</td>
<td>Once via IV</td>
<td></td>
<td></td>
<td>Once via IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>Bone pain, fever</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rituximab (Rituxan)</td>
<td>Infusion-type reactions, fever, rigors and/or chills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intrathecal Chemotherapy</td>
<td>Headache, nausea, vomiting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
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</tr>
</tbody>
</table>

*If you develop a fever >100.4°F or other signs of infection, please call the hematology clinic. Please let your provider know if you develop any of the side effects listed above.

Hematology clinic can be reached at _________________

Reviewed by Patient Education:
Appendix

Patient Education: Moxetumomab

Schedule:
1. You will be required to have labs drawn within 7 days prior to starting chemotherapy.
   - Chemotherapy starts on Day 1.
   - Arrive at Lab draw in the morning to have labs checked. Then, proceed to the Infusion Center to check in.
   - Next, you will receive IV hydration, pre-medications, followed by moxetumomab. You will also receive IV hydration after moxetumomab
   - A provider will come see you after your labs are checked and before you receive chemotherapy.
   - You should drink at least twelve 8-oz glasses of fluid every 24 hours from Day 1 through Day 9 of each cycle.
   - Avoid over eating or drinking products with high potassium (examples: Gatorade®, bananas, spinach).
2. Depending on your disease, you might be assessed on Day 2 and Day 4. If there are lab abnormalities or symptoms that require close monitoring, additional assessment visits may be scheduled for up to day 10.
   - You may receive extra IV fluids, transfusions, or electrolytes if needed.
3. Two possible side effects include capillary leak syndrome (CLS) and hemolytic uremic syndrome (HUS). It is important to watch for signs and symptoms of these conditions while you are at home.
   - Signs and symptoms of CLS: weight gain (> 5.5 lbs from day 1), low blood pressure, dizziness
   - Signs and symptoms of HUS: decreased urination, blood in urine or stool, unexplained bruising or bleeding, extreme fatigue
4. In the future, you may receive additional cycles of this therapy in the outpatient setting.

Prescriptions:
1. You might need to take the following medications at home to prevent possible side effects of moxetumomab
   - Aspirin 81 mg (baby aspirin) once daily days 1 – 8
   - Dexamethasone 4 mg
   - Other

2. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compazine (prochlorperazine)</td>
<td></td>
<td></td>
<td>Take 1 tablet as needed up to 4 times daily</td>
</tr>
<tr>
<td>Ativan (lorazepam)</td>
<td></td>
<td></td>
<td>Take 1 tablet as needed up to 3 times daily</td>
</tr>
</tbody>
</table>

- Prescription(s) for __________________________ were sent to __________________________ pharmacy.
Appendix

Calendar: Moxetumomab

Moxetumomab – abbreviated regimen overview

*Possible Side effects:
  - Fluid retention, blurred vision, fatigue, nausea, headache, fever, infusion reaction, capillary leak syndrome, hemolytic uremia syndrome, kidney impairment, electrolyte abnormalities (low calcium, low phosphorus, low sodium, low magnesium, low potassium)

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumoxiti*</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
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</tr>
<tr>
<td></td>
<td>Day 8</td>
<td>Day 9</td>
<td>Day 10</td>
<td>Day 11</td>
<td>Day 12</td>
<td>Day 13</td>
<td>Day 14</td>
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<td></td>
<td>Day 15</td>
<td>Day 16</td>
<td>Day 17</td>
<td>Day 18</td>
<td>Day 19</td>
<td>Day 20</td>
<td>Day 21</td>
</tr>
</tbody>
</table>

*If you develop a fever >100.4°F or other signs of infection, please call the hematology clinic. Please let your provider know if you develop any of the side effects listed above.

Hematology clinic can be reached at ________________

Reviewed by Patient Education
Patient Education: Tagraxofusp

Schedule:
1. You will be required to have a central line and labs drawn within 7 days prior to starting chemotherapy. You will also have labs drawn daily while you receive chemotherapy.
   • You will receive your first cycle of tagraxofusp in the hospital (Inpatient)
     ▪ You may receive subsequent cycles outpatient in the infusion center
   • Chemotherapy starts on Day 1 and continues for 5 days. Cycles are started every 21 days.
   • Initial tolerance to Tagraxofusp may vary. For your safety, doses might be skipped and made up within 10-days of starting treatment.
2. Starting Day 1 _______________[date]
   • Arrive at lab draw in the morning. Once labs are drawn, proceed to the Infusion Center.
   • You will be required to check a daily weight on the IPOP scale.
   • After you receive pre-medications and chemotherapy, you will be monitored for infusion-reactions for at least two-hours in the Infusion Center.
   • Possible symptoms include fever, chills, and/or rash.
   • Depending on your symptoms, weight and labs, you might receive extra infusions.
3. A possible serious side effect of tagraxofusp is capillary leak syndrome (CLS). It is important to watch for signs and symptoms of this condition while you are at home.
   • Signs and symptoms of CLS: weight gain (> 3 lbs from prior day of treatment), low blood pressure, dizziness
4. You will be required to have daily labs and provider visits after receiving this chemotherapy. The frequency of visits may be reduced based on your symptoms and laboratory values.

Prescriptions:
1. Prescriptions were sent to _______________ pharmacy.
   ▪ Allopurinol 300mg [one or twice] daily
2. You may be given antibiotics to help prevent infection during chemotherapy.
   ▪ Acyclovir 800mg twice daily (continue for entire duration of treatment)
   ▪ Ciprofloxacin 500mg twice daily
   ▪ Other _______________
3. Do you have any of the following nausea medications available at home?

<table>
<thead>
<tr>
<th>Medication</th>
<th>Yes</th>
<th>No</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zofran (ondansetron)</td>
<td></td>
<td></td>
<td>Take 1 tablet as needed up to ___ times daily</td>
</tr>
<tr>
<td>Compazine (prochlorperazine)</td>
<td></td>
<td></td>
<td>Take 1 tablet as needed up to 4 times daily</td>
</tr>
<tr>
<td>Ativan (lorazepam)</td>
<td></td>
<td></td>
<td>Take 1 tablet as needed up to 3 times daily</td>
</tr>
</tbody>
</table>

   • Prescription(s) for _______________ were sent to _______________ pharmacy.
4. You may experience constipation during your treatment. For relief, stimulants and stool softeners (Senokot/Senna, MiraLax, Colace (docusate)) are available over-the-counter (OTC) at your local pharmacy.
**Tagraxofusp** — abbreviated regimen overview

*Possible side effects:*
- Weight gain, swollen extremities, low blood pressure, high blood pressure, increased heart rate, infusion-reaction (fever, chills, rash), liver injury, nausea, constipation, vomiting, diarrhea, decreased blood counts and infection, muscle pain, headache, difficulty breathing, difficulty sleeping, fatigue, capillary leak syndrome, increased blood glucose.

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td>Once via IV</td>
<td><em>might receive once via IV</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 8</th>
<th>Day 9</th>
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<th>Day 11</th>
<th>Day 12</th>
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<td></td>
<td><em>might receive once via IV</em></td>
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<table>
<thead>
<tr>
<th>Day 15</th>
<th>Day 16</th>
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</table>

*If you develop a fever >100.4°F or other signs of infection, please call the hematology clinic. Please let your provider know if you develop any of the side effects listed above.*

Hematology clinic can be reached at ________________

Reviewed by Patient Education
Frequently Asked Questions

Responses from Moffitt Cancer Center
Why did you decide to transition these regimens to the outpatient setting?
Lack of hospital beds and delays in scheduling chemotherapy led to patient dissatisfaction. Beyond bed availability, there was an understanding that patients didn’t want to be in the hospital and being there over and over again for something routine felt like it made their overall experience worse. There are many other potential reasons but these have been primary drivers.

How did you get started?
We built a cross-functional leadership team that included all stakeholders (Nursing, Pharmacy, Physicians, PA’s and ARNP’s, Social Work, IT, etc.) and asked this group to work through the issues associated with adoption in their areas. It was important to be gradual and do one chemotherapy regimen at a time and even one patient at a time so that everyone could see that this worked and was safe. Doing something new is always hard but once there were early successes everyone was bought in for the long term.

How long did “getting started” take?
9-12 months from idea to first patient receiving Arm A of HyperCVAD in the outpatient setting. Each regimen since then has taken less time (generally 3-6 months from idea to implementation).

How difficult was “getting started”? 
This could have been very difficult without buy-in from the stakeholders listed above. One of the critical issues is physician buy-in. Physicians often like to be innovative and they like to see their patients do well and be happy so these things would generally overwhelm any physician specific resistance to change. Thinking from the standpoint of the physician, at our site, this allowed their patients to get the same high quality care, just faster and they didn’t have to be in the hospital. One concern was around the amount of pages that might be received by faculty overnight, but our physicians typically experience less than one page per month regarding these patients (on average one page per quarter) and so there was broad support once it was understood that this was going to be less complicated than originally anticipated.

What were the smartest decisions that were made regarding this change?
Creation of a cross functional, empowered leadership team was probably the most important decision. We needed everyone to come together and to make decisions together. Probably the second smartest decision was hiring a full time Physician Assistant to run this service and see these patients daily. It prevents a lot of uncertainty for the patient and subsequently heads off potential readmissions due to this uncertainty, which might not be grounded in objective reasons for admission.
Frequently Asked Questions: General

What would you change about implementation?
Initially, there was a thought that this would happen very quickly. Specifically, in the first year we budgeted for hundreds of hotel nights for presumed future patients who would require lodging assistance. However, in year 1, demand for hotel nights and the first regimen overall was much smaller than we anticipated (<100 hotel nights). Interestingly, because we overestimated the first year, there was then a tendency to underestimate in future years and it became a challenge to handle 100% growth year after year without different parts of the system decompensating. For perspective, our organization has grown 7-10% per year for the last 5 years and this program has grown 100% each year over the same time period.

How much time did you need from team members in the early stages?
We had a kickoff meeting and then about 4-6 stakeholder meetings to get the first regimen live. There was a lot of back and forth communication when the first group of patients was in the outpatient setting, but much of that happened via email since the kinks were already worked out. Each additional regimen has been handled by a smaller team rather than the initial team that has move into an oversight or steering role and meets rarely several years into the process. With regards to FTE requirements for ongoing maintenance of a service with >2,000 hospital days per year, we would recommend consideration of the following:

- 0.25 IT/Programming FTE
- 1.0 to 1.5 PA/ARNP FTE
- 1.0 to 1.5 PharmD FTE
- 0.1 to 0.2 Physician FTE

Is this possible at any site?
Yes, if you build a strong team, follow the Toolkit, and carry out the plan. Most concerns come from the fear of change and once people see happy patients, a lot of that resistance to change fades.
Frequently Asked Questions: Challenges associated with adding infusion regimens

How can my organization help patients, physicians, nurses, etc. feel comfortable making this change?
Other than general change management recommendations, probably the most important thing we did was to refer to this change as a direct translation of inpatient care delivery into the outpatient setting. Inpatient nurses are trained the same as outpatient nurses for these regimens. The patients are still seen each day by a PA or an ARNP, just as they would if they were in the hospital. The physician still signs the notes each day for these patients and is available for questions. It helped to also have assurances that there was a bed for these patients if needed. In 5 years we have run into a bed issue once but otherwise it’s almost never needed.

Will our organization need to amend our pharmacy, inpatient, and/or outpatient clinic hours?
As a general rule, no. Regimens like HiDAC or HyperCVAD do require chemotherapy to be delivered 10 hours apart, but the majority of large infusion centers are open 10-12 hours each weekday. As a result, you probably will not need to extend hours. The clinic hours would also not be extended as these patients are seen in the infusion center rather than in the outpatient clinic.

Will our organization need to make changes in pharmacy staff during the transition of infusion services to IPOP?
A large organization will employ 8-10 pharmacy staff members in their infusion center each weekday and then presumably fewer on the weekends (2-3). In our experience, these numbers of pharmacists have been more than enough to handle heavy outpatient chemotherapy volumes, as well as the addition of these regimens and any adjustments associated with these transitions.
Frequently Asked Questions:
Challenges faced during implementation

Some of our patients don’t have subcutaneous ports or picc lines. How do we accommodate them?
Nearly all of the regimens in this Toolkit will require central access. This facilitates delivery via pump and reduces the risk of the need for urgent access in the middle of a cycle. The recommendation for most patients receiving vesicant and irritant chemotherapeutics is leveraging a central line or at least a midline, which could later be removed at the end of the cycle.

What pumps do you use?
InfuSystem Holdings, Inc., however, the important thing is not the company but an understanding of how the pump works and how the company will assist the team and the patient with troubleshooting the pumps.

How will our institution troubleshoot infusion pump issues?
This is critical because in the middle of the night someone may need to address issues. The vast majority of the pump issues are rare, but are handled overnight by providing the patient with instructions to call InfuSystem (or your respective pump provider) for issues with their pump. If they are not immediately available, the patient is instructed the call the charge nurse on the primary chemotherapy floor where these regimens are delivered. While pump issues are rare, this is an important process to have in place.

How will our organization accommodate patients who must travel long distances for treatment?
In our experience, approximately 50% of patients require assistance with housing (either arranging it or paying for it). Financial assistance is offered to those in need, and many hospitals have agreements with local hotels to provide lower cost lodging for patients. Lower risk patients are encouraged to travel to and from infusion appointments and stay at home, assuming they meet guidelines for distance, compliance, etc. Financial assistance for hotel rooms for patients who meet the criteria for financial need is provided by both operational funds and funds through a foundation associated with our organization. Criteria for financial need in this circumstance are the same as the criteria for charity care overall at our organization.

What changes would we need to make to our scheduling system to accommodate these new regimens?
Likely, none. These are small numbers of patients in the overall population (3-7 per day), and in an infusion center that sees 300 patients per day, a 1% increase is not noticeable. The area where this is noticeable is on the inpatient side where suddenly a 3% increase in bed availability provides a lot of flexibility.
Is there risk to our organizational finances if we try to do this for patients?
This was the first question at our organization. Before we moved forward with our initial regimen (HyperCVAD Arm A) there was a financial analysis done that showed we would lower the cost of care for the regimen by about 1800 dollars and that our overall revenue from each outpatient case would be lower than a corresponding inpatient case. When we added a backfill of these inpatient beds, each case that was transitioned into the outpatient setting was actually favorable to budget. Thusly, because we are facing consistent high demand, there was good support for moving this regimen into the outpatient setting.

Will my hospital system lose money on each of these regimens?
No, probably not. Obviously, the hospital system still generates revenue on each of these cases, just at a lower cost and revenue when it is done as an outpatient. In our opinion, healthcare payment models are changing quickly and anything that can be done in a setting other than a high cost inpatient bed will be required within a few years as it reduces the cost of care without compromising quality. We’ve seen this with full outpatient surgeries in our hospital that previously required long inpatient stays and we believe chemotherapy will go in the same direction.

Are there other examples of the finances around this?
Yes, recently published in the JOP there is an article that shows reduced costs of ~20,000 dollars for each cycle of DA-EPOCH transitioned into the outpatient setting. Our internal data suggests that our transition of HiDAC into the outpatient setting is also highly favorable to budget and we intend to publish this data as well. Overall, the literature is growing around this being better for patients, better for payors and better for hospitals who can then care for their sickest referrals in newly freed up beds. Taking that in aggregate, this toolkit is likely to be the start of a larger movement across the country to shift towards outpatient and home based care.
What about natural disasters, huge blizzards and other oddities?

Several years into implementation, there was a major hurricane that hit the area and there were half a dozen patients on this outpatient service. Considering that roads could be closed and patients might not be able to get to the hospital, we decided to admit all of the patients on this service for 24-48 hours until the risk was reduced. This was the right decision as many roads were closed and there was no disruption of service for these patients. If this outpatient service were undertaken in an area with frequent heavy blizzards, we would recommend admitting these patients if there is a significant risk they would not be able to travel to appointments. Similarly, if it were to snow in an area where it snows rarely, we would recommend admitting these patients before the storm since the area could be unable to handle the storm in an effective way, leading to road closures and disruptions for patients.
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