Guidelines for Ambulatory Management of Patients with COVID + or presenting from "Hot Zones", including Extended Care Facilities, Group Homes and Correctional Facilities

Situation: Patients who are confirmed COVID + or present from "high-risk" areas, including Extended Care Facilities (ECFs), Group Homes (GH), Correctional Facilities (CF) and "hot zones", may require direct management or supportive care for their hematologic or oncologic diagnosis.

Background: Rapidly increasing burden of COVID-19 throughout Connecticut and neighboring states is increasing the number of patients with confirmed COVID +, or at high risk for COVID positivity, who will need to receive appropriate care for their hematologic or oncologic diagnosis. These patients represent a risk to worsen the severity of their own COVID illness and/or increase the risk of exposure to other patients and health care workers.

Assessment: Patients can be divided into 3 categories for consideration:

- Confirmed COVID positive patients with varying severity of illness (mild, severe and convalescence);
- Patients arriving from ECFs, GF's,CF's; these patients are highly suspicious, but asymptomatic. This definition may expand over time.
- Patients presenting from geographic "high-risk" areas, including New York and population dense areas of Connecticut. The rapidly increasing number of patients represented by a geographic definition exceeds the resources available to offer private rooms and maximal PPE to treat this population

Guiding Principles

1. Ensure the safety of other patients and staff, by reducing exposure to actively infected patients.
2. Accommodate patients who require medical management or supportive care.

Recommendations:

1. **Patients from ECF, GF, CF but COVID indeterminate**
    a. Determine if patient requires an in-office visit
        i. Limited strictly to patients in which delay in treatment would place them in jeopardy from their disease, as determined by local Medical Director
        ii. Disease cannot be managed longitudinally by telehealth (i.e. oral chemotherapy or endocrine therapy)
    b. A COVID test within 24 hours of appointment is required (see below).
        i. COVID positive – follow COVID Positive Pathway
    c. If rapid testing is **not available**, or test negative, the following guidelines should be followed:
        i. On-site Visit
            1. Patient must pass clinical and temperature screening **prior to** entering facility
                a. Positive screen: Follow pathway for positive screen, speak to provider
                b. If assessment at higher level needed, refer patient to Smilow Rapid Evaluation Clinic (SREC).
            2. **All staff should wear appropriate PPE for presumed infected patient, including respirator, face shield, gown and gloves.**
                a. If PPE not available, appointment should be rescheduled to obtain PPE or discuss alternative site (see below).
            3. Patient should receive all components of their care (check in, labs, vital signs, provider visit, treatment) in *a single* predesignated location (private room) within the office.
                a. Patient should be roomed as soon as possible and placed in private room with the door closed

   b. Schedule visit at a time that minimizes number of people in clinic, but allows time for completion of planned treatment; may require coordinating schedule one week in advance
   c. When possible, cohort patients to single day of week, allowing for deep clean afterward
4. Patients should wear a mask at all times in the clinic, even in an exam room. Patients should only remove mask if required for patient care activities (i.e. an oral exam).
5. Use dedicated or disposable non-critical patient-care equipment (e.g., blood pressure cuffs), when possible. If equipment will be used for more than one patient, clean and disinfect such equipment according to manufacturer's instructions before use on another patient.
6. Cleaning recommendations – turn over similar to contact precautions room – wipe down all surfaces with disinfectant wipes. If patient removes mask at any time during visit, room must sit empty with door closed for one hour before cleaning-per YNHHS Ambulatory COVID-19 Guidelines.

2. Patients with confirmed COVID positive illness

a. Patients requiring systemic therapy for malignancy (excluding endocrine therapy).
   i. Patients should not receive or resume systemic therapy for malignancy until completion of convalescence for COVID. (Note CDC guidelines below for clinical convalescence)
   ii. In the rare scenario that a patient must receive anti-cancer therapy while still COVID positive, agreement between two physicians is required (follow existing algorithm for non-standard chemotherapy – primary attending discussion with Kerin Adelson, Smilow Deputy CMO or Anne Chiang, Smilow Chief Network Officer)
      1. Examples include highly-aggressive lymphoma, mediastinal germ cell tumor
      2. Hospitalization for treatment is likely warranted
         a. Location – designated site to be determined with appropriate PPE, experience and equipment. (See Considerations below)
         b. Direct verbal communication between primary attending and either inpatient hematology or oncology consult attending required
         c. Written documentation of plan, including consent and goals of care discussion, and orders provided by primary attending
      3. Outpatient treatment planned
         a. Consider risk for hypersensitivity reaction and need for emergent care
            i. If risk high, delay treatment or inpatient treatment
         b. Patients should receive treatment at SREC or designated regional site
            i. Direct verbal communication and between primary attending and SREC APP required
            ii. Written documentation of plan and orders provided by primary attending
            iii. If volume of patients expands beyond SREC capability, utilize regional sites

b. Patients requiring supportive care

i. Includes IV hydration, blood product transfusion, growth factor support
ii. Triage urgency of supportive care needs
iii. Explore if home care is an option
iv. If necessary, patients should receive treatment at SREC or regional sites (see Appendix 2 &3)
v. Patients should return to home site after convalescence per CDC and Yale New haven Health Occupational Health guidelines (see Appendix 1)

c. Disease Specific Guidelines for Hematologic Malignancy
   i. Guiding Principles:
      1. Focused on hematology patients with known diagnostic or suspicion of hematologic malignancies, and with COVID positivity or high risk of COVID based on contact or Hot Zone
      2. Does treatment cause any of the following in the next 2-4 weeks: severe cytopenias, significant immunosuppression, or a potential worsening of the COVID related symptoms (hyper acute inflammatory response, coagulopathy)?
      3. Discussion with the patient of the risk/benefit of the different options needs to be clearly discussed and clearly documented with reference to the COVID pandemic.
   ii. Treatment algorithm for general cases
      1. Can treatment be **safely** delayed for 2-4 weeks?
         a. If Yes, delay initiation of therapy
         b. If No, can the treatment be modified to alternative therapy or changed to maintain safety and preserve the **general oncologic outcome** of patient without impact on COVID prognosis?
            i. If Yes, proceed with temporizing measures/alternative therapy (examples include, hydroxyurea, TKI)
            ii. If no, follow guidelines as follows:
               1. **Agreement between two physicians is required (follow existing algorithm for non-standard chemotherapy – primary attending discussion with Deputy CMO – Kerin Adelson, MD; or Chief Network Officer – Anne Chiang, MD)**
               2. Hospitalization for treatment is likely warranted
               3. Location – designated site to be determined with appropriate PPE, experience and equipment. (See Considerations below)
               4. Direct verbal communication and between primary attending inpatient hematology attending required
               5. Written documentation of plan, including consent and goals of care discussion, and orders provided by primary attending

   iii. Treatment algorithm for maintenance therapy/continuous treatment (Myeloma, FL, long term CLL, ALL maintenance) – consistent with ASH guidelines
      1. Does maintenance therapy cause severe cytopenia or significant immunosuppression or potentially worsen COVID related symptoms (hyper acute inflammatory response, coagulopathy)?
         a. If yes: HOLD MAINTENANCE for COVID proven cases until completion of convalescence

i. Includes maintenance for myeloma, ALL and rituximab

b. If no, continue therapy with close monitoring for COVID positive patients with no or mild COVID clinical symptoms.
   i. Includes treatment for CLL, MPD, CML and AML continuous treatment
   ii. Hold maintenance for patients with severe clinical presentation.

3. High Risk Geographic Zones

a. Patient triage for in-office visit
   i. Limited strictly to patients in which delay in treatment would place them in jeopardy from their disease, as determined by local Medical Director
   ii. Disease cannot be managed longitudinally by telehealth (i.e. oral chemotherapy or endocrine therapy)

b. A COVID test within 24 hours of appointment is required (ideal state).
   i. COVID positive – follow COVID Positive Pathway
   ii. If rapid testing is not available, or test negative, the following guidelines should be followed:
      1. Patient must pass clinical and temperature screening **prior to** entering facility
         a. Positive screen: Follow pathway for positive screen, speak to provider
         b. If assessment at higher level needed, refer patient to SREC or local ED
      2. Patient will be treated with standard precaution

APPENDIX 1: CDC GUIDELINES FOR DISCONTINUATION OF ISOLATION

The decision to discontinue isolation should be made in the context of local circumstances. Options now include: 1) a time-since-illness-onset and time-since-recovery (non-test-based) strategy, and 2) test-based strategy

Time-since-illness-onset and time-since-recovery strategy (non-test-based strategy)*

Persons with COVID-19 who have symptoms and have been directed to care for themselves at home **may** discontinue isolation under the following conditions:

- At least 3 days (72 hours) have passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **AND**
- Improvement in respiratory symptoms (e.g., cough, shortness of breath); **AND,**
- At least 14 * days have passed *since symptoms first appeared*.*Note CDC guidelines are 7 days but we are following our own Occupational Health guidelines.

Test-based strategy (simplified from initial protocol) previous recommendations for a test-based strategy remain applicable; however, a test-based strategy is contingent on the availability of ample testing supplies and laboratory capacity as well as convenient access to testing. For jurisdictions that choose to use a test-based strategy, the recommended protocol has been simplified so that *only one swab is needed at every sampling*.

Persons who have COVID-19 who have symptoms and were directed to care for themselves at home may discontinue isolation under the following conditions:

- Resolution of fever without the use of fever-reducing medications **and**
- Improvement in respiratory symptoms (e.g., cough, shortness of breath) **and**
- Negative results of an FDA Emergency Use Authorized molecular assay for COVID-19 from at least two consecutive nasopharyngeal swab specimens collected ≥24 hours apart** (total of two negative specimens). See Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) for specimen collection guidance.

Persons with laboratory-confirmed COVID-19 who have not had <u>any</u> symptoms:

- May discontinue isolation when at least 14* days have passed since the date of their first positive COVID-19 diagnostic test and have had no subsequent illness provided they remain asymptomatic. *Note CDC guidelines are 7 days but we are following our own Occupational Health guidelines.
- For 3 days following discontinuation of isolation, these persons should continue to limit contact (stay 6 feet away from others) and limit potential of dispersal of respiratory secretions by wearing a covering for their nose and mouth whenever they are in settings where other people are present
- In community settings, this covering may be a barrier mask, such as a bandana, scarf, or cloth mask. The covering does not refer to a medical mask or respirator.

APPENDIX 2: "GUIDELINES FOR AMBULATORY MANAGEMENT OF PATIENTS WITH COVID+ OR PRESENTING FROM HOT ZONES"

- Testing 24 hours prior to visit as available for patients not already known to be COVID+.
- Treatment and/or supportive care is determined necessary based on clinical condition; consider treatment at Smilow Rapid Evaluation Clinic (SREC) prior to other Regional Location.

For COVID+ Patients:

- Primary physician reviews necessity of treatment with Kerin Adelson, Smilow Deputy CMO, or Anne Chiang, Smilow Chief Network Officer and documents decision to treat/not treat in patient's EMR.
- Treat inpatient if patient status warrants, or treat at SREC if available capacity.

For COVID Indeterminate Patients:

- Primary physician reviews necessity of treatment with local Medical Director
- Indeterminate patient passes entrance screening

On-site Guidelines

- Patients will be cohorted to 1-2 days per week based on volume/need.
- Use of private room, PPE and disposable equipment.
- Nursing ratio is one nurse to a maximum of two patient PUI's.
- Terminal clean of room at end of day

Follow Smilow SOP for "Treating Patients in an Alternate Smilow Ambulatory Location" including:

- *Sending team calls SREC to make appointment and notifies ECF, CF or GH of change in visit location. Sending team creates telehealth visit with sending provider one hour after SREC infusion appointment time.*
- Telehealth visit is scheduled in primary oncologist epic department. SREC visit is scheduled as infusion/injection etc. visit in SREC Epic department.
- Handoff Communication
- Coordination of Patient Care
- Sending team confirms prior authorization and signs treatment plan/ orders in advance of presenting at Regional Site.
- Upon arrival to Regional Site lab work drawn and COVID rapid testing*completed. *Currently testing is only available at SREC. When lab work and COVID test resulted, patient has telehealth visit with primary oncologist and decision made to treat, modify or hold treatment.
- SREC APP provides coverage for onsite physical assessment, hypersensitivity management, and other acute issues that may arise.
- First time treatments, patients with hypersensitivity history, and clinical trial regimens warrant a discussion of inpatient verses outpatient based on hypersensitivity risk. These patients should be the exception.
- Clinical trials require staff be educated appropriately.

APPENDIX 3: REGIONAL SITES FOR COVID+ AND/OR ECF, GH OR CF PATIENTS APPROVED FOR TREATMENT

Regional Site	Geographic Sites Served
St. Francis Women's Infusion Center	St. Francis

	Glastonbury
	Torrington
	Waterbury
Bridgeport Hospital WT7	Derby
	Trumbull
	Fairfield
Greenwich Hospital Inpatient 3rd floor (Bendheim)	Smilow at Greenwich Cancer Center
Smilow Rapid Evaluation Clinic	New Haven
	Orange*
	North Haven
	Guilford
Smilow Waterford	Waterford
	Westerly
***Patient may be offered multiple sites as options to receive their treatment.**	