# Therapeutic Carbohydrate Reduction Aspire Program SOP

### SOP

Western NC VA Health Care System
Asheville, 28805

**Signatory Authority:**
Chief of Whole Health
Chief of Primary Care
Chief of Pharmacy

**Responsible Owner:**MOVE! Coordinator

**Service Line:**
Whole Health, Pharmacy, Primary Care

 **Effective Date:**

 **Recertification Date:**

## PURPOSE: The Whole Health Service along with The Department of Primary Care and The Pharmacy Service Line, as part of a High Reliability Organization, are committed to continuous process improvement (CPI). We have identified a need for a lower carbohydrate approach to educating, treating, and supporting veterans with metabolic syndrome, especially those who are overweight or obese and who also having a diagnosis of diabetes. Due to a high degree of insulin resistance, these populations are challenged to lose weight and improve glycemic control with standard methods of care (CITATION).

## This set of Standard Operating Procedures (SOP) serves to outline the Therapeutic Carbohydrate Reduction (TCR) Aspire Program policy and procedures, ensuring a seamless pairing of disciplines from the Whole Health, Primary Care, and Pharmacy Service Lines, resulting in timely care-coordination to minimize side effects from TCR dietary changes while ensuring agile de-prescribing of medications and thorough communication between all affected parties.

1. **POLICY:** The Whole Health, Primary Care, and Pharmacy Services are committed to collaborating with clear and intentional roles and responsibilities as we jointly serve those Veterans engaged in the TCR Aspire Program.
2. **ACTION:**
	1. **TCR Aspire Patient Education Materials**
		1. Development:
		2. Printing:
		3. Mailing:
		4. Facilitating and Presenting TCR Aspire:
		5. Communication of Medication Changes to care team.
	2. **TCR Aspire Clinic and Note Templates:**
	3. **Aspire Participants:**
		1. Referrals to TCR Aspire:
		2. Acceptance to TCR Aspire: Review of Inclusion/Exclusion Criteria
		3. Scheduling into TCR Aspire:
	4. **Laboratory Markers:**
		1. Ordering:
			1. Pre-Program Labs:
			2. During-Program Labs:
			3. Post-Program Labs:
		2. Ordering Self-Monitoring Devices (Blood Pressure Cuff, Glucometer, Testing Strips.
		3. Communication of Results:
		4. Actions in response to Results: see Medication Changes
		5. \*\*\*Warfarin Exception
	5. **TCR Aspire Class Facilitation and Presentations:**
	6. **Medications Changes:**
		1. De-Prescribing of Medications
		2. Patient Education on Medication Changes
		3. Communication of Medication Changes to Care Team Members
	7. Discharge from TCR Aspire Clinic
3. **PROCEDURES:**
	1. **TCR Aspire Patient Education Materials**
		1. Development: The bulk of the TCR Aspire Patient Education Materials will be developed by The Whole Health Service’s MOVE! Coordinator (MC) with feedback provided by the participating Primary Care Clinical Pharmacist Practitioner (CPP). The Primary Care CPP will develop session 1 of 17, exploring potential adverse reactions to a TCR dietary approach, hypoglycemia protocol and the process for communicating with the Primary Care CPP to ensure appropriate de-prescribing of medications.
		2. Printing: The MOVE! Coordinator will place orders with print shop for all TCR Aspire Education Materials.
		3. Mailing: A Whole Health Service Advanced Medical Support Assistant (AMSA) will mail TCR Aspire Patient Education Materials to participants 2 weeks prior to the initial class start date.
	2. **TCR Aspire Clinic and Note Templates:** The Whole Health Service will work with CACs to create a TCR Aspire Clinic and TCR Aspire Note Templates.
	3. **Referrals, Acceptance and Scheduling Aspire Participants:**
		1. Referrals to TCR Aspire: Patients will be referred to TCR Aspire by PCPs, PC CPPs, Whole Health Coaches (WHCs), and Registered Dietitians (RDs).
		2. Acceptance to TCR Aspire: The MOVE! Coordinator (MC) will determine appropriateness of patient referrals based on inclusion and exclusion criteria.
			1. Inclusion Criteria
				1. Pilot: Type 2 diabetes and on a diabetes medication and BMI >25.
				2. Expansion: Pre-diabetes/Insulin Resistance; Metabolic Syndrome; Non-Alcoholic Fatty Liver; Polycystic Ovarian Syndrome.
			2. Exclusion Criteria: Type 1 diabetes; History of Keto-Acidosis; History of myocardial infarction, stroke, angina, or coronary insufficiency within the last 6 months; diabetic retinopathy requiring treatment; serum creatinine >2.0 mg/dL; impaired hepatic function (bilirubin >2mg/dL, albumin <3.5 g/dL); cholelithiasis or biliary dysfunction, cancer requiring treatment in the past 5 years, with the exception of non-melanoma skin cancer; chronic infectious disease requiring ongoing treatment; other chronic diseases or conditions likely to limit lifespan to <6 years; non-English speaking; unable or unwilling to participate in group sessions, unwilling to engage in diet and/or lifestyle behavioral changes, failure to obtain pre-program labs within 2 weeks of start of TCR Aspire; weight loss of >10% in past 6 months; currently pregnant or nursing, or planning to become pregnant during the program; major psychiatric disorder (e.g. schizophrenia, bipolar disorder) currently uncontrolled; excessive alcohol intake (acute or chronic) defined as average consumption of 3 or more alcohol-containing beverages daily or consumption of more than 14 alcoholic beverages per week.
		3. Scheduling into TCR Aspire: A Whole Health Service Advanced Medical Support Assistant (AMSA) will schedule veterans into the TCR Aspire Clinic.
	4. **Laboratory Markers:**
		1. Ordering: Pre-Program Labs and Post-Program Labs will be ordered by MOVE! Coordinator. Labs: HgbA1C, Lipid Panel, Fasting Glucose, Serum Creat/eGFR panel, Liver Function Panel
			1. Pre-Program Labs: if labs results are available within the past 30 days, we will not re-order labs. If labs are >30days out, MOVE! Coordinator will order pre-labs and notify Veteran of need to obtain labs within the first 2 weeks of class start date for continued participation in TCR Aspire.
			2. During-Program Labs: It will not be necessary to recheck labs during the course unless patients present with symptoms that may be related to laboratory abnormalities.
			3. Post-Program Labs: Labs will be ordered by MOVE! Coordinator 3-weeks prior to the completion of class. Veterans will be encouraged to obtain labs within the final 2 weeks of TCR Aspire (weeks 14-16). Veteran’s labs will remain eligible for review if obtained up to two weeks after the final TCR Aspire class.
		2. Ordering home monitoring devices (Blood Pressure Cuff, Glucometer, Testing Strips) will be ordered on an as needed basis by TCR Aspire PharmD.
		3. Communication of Results: lab results will be communicated to Veterans using Secure Messaging (MyHealtheVet) or mail if a Veteran does not have MyHealtheVet prior to week 3 of TCR Aspire and prior to week 16 of TCR Aspire or within 2 weeks of TCR Aspire completion.
		4. Actions in Response to Results: see Medication Changes
		5. \*\*\*Warfarin Exception: if a Veteran is on warfarin/coumadin, the anti-coagulation clinic will be notified of Veterans enrollment in and discharge from TCR Aspire so they can best manage changes to anti-coagulant medications.
	5. **TCR Aspire Class Facilitation and Presentations:**
		1. Whole Health Coach serves as facilitator for TCR Aspire responsible for placing RTC for ongoing participation, monitoring and tracking attendance, setting-up participants for ANNIE, tracking weights in spreadsheet from ANNIE and entering weights in CPRS, and communicating no shows and cancellations to AMSA.
		2. MOVE! Coordinator and Whole Health Coach will serve as primary instructors for TCR Aspire with assistance from PC CPP for session 1 of 17-week series. Lead instructor for each week are as follows:
	6. **Medication Changes:**
		1. De-Prescribing of Medications: TCR Aspire PharmD will serve as primary diabetes prescriber for diabetes medication changes. TCR Aspire PharmD will consult with PCP or other Prescribing entity on a per case basis.
		2. Patient Education on Medication Changes: TCR Aspire PharmD will educate Veterans on medication changes.
		3. Communication of Medication Changes to Care Team Members: TCR Aspire PharmD will co-sign PCP and/or Specialty Provider (Endocrine, Nephrology, Risk Reduction CPP) to changes in medications through Computerized Medical Record.
	7. **Discharge from TCR Aspire Clinic**: TCR Aspire PharmD would enter a note summarizing medication changes made over the course of the 16-weeks and recommendations for ongoing changes/next steps. MOVE! Coordinator will addend note to add changes in weight and other behavioral changes.

## 5. ASSIGNMENT OF RESPONSIBILITIES:

1. **Whole Health and Primary Care Service Chiefs:**
2. Review and approve TCR Aspire Program SOP
3. Provide Staffing as needed to support TCR Aspire Program.
4. **MOVE! Coordinator:**
5. Develop TCR Aspire Materials
6. Order TCR Aspire Materials from the Print Shop
7. Review referrals for appropriateness of TCR Aspire Program based on inclusion and exclusion criteria.
8. Order Pre-Program and Post-Program Labs
9. Lead Instructor for the following weeks in 17-week TCR Aspire Program: ???
10. Notify TCR Aspire PharmD via co-signature to note in Computerized Medical Record of Veteran reports of hypoglycemia, hypotension, and/or any side-effects related to dietary intervention following each TCR Aspire Session.
11. Addend PharmD TCR Discharge Note to include changes in weight and behavioral changes as noted.
12. **Primary Care CPP = TCR Aspire PharmD:
Hypoglycemia, hypotension, any side effects related to dietary intervention (muscle cramps, nausea, headaches, fatigue,**
13. Develop TCR Aspire Session 1.
14. Meet individual with each participant following session 1.
15. Meet with TCR Aspire Participants upon Veteran, MOVE! Coordinator, or Whole Health Coach notification of Veteran reporting hypotension, hypoglycemia, or side-effects related to dietary intervention (muscle cramps, nausea, headaches, fatigue).
16. Co-sign PCP and other specialty prescribers when changes to medications occur.
17. Place TCR Aspire Discharge note reflecting changes to medications that occurred during TCR Aspire, changes to laboratory markers and next steps for providers who will take over Veterans DM care**.**
18. Order Blood Pressure Cuff, Glucometer and Testing Strips as needed.
- Oral medications only will test once daily and as needed for hypoglycemic treatment exploration. Insulin test once or more per provider guidance.
19. **Whole Health Coach:**
20. Co-Facilitate 16-week TCR Aspire Program
21. Lead Instructor for the following weeks in 17-week TCR Aspire Program:
22. Submits RTCs for continued programming at weeks 2, 6, and 10.
23. Works with MOVE! Coordinator to enroll participants in Annie, capture weights from Annie to spreadsheet and enter weights into CPRS.
24. Notifies TCR PharmD through co-signature in Computerized Medical Record of Veterans who report hypoglycemia, hypotension, and/or side-effects of dietary intervention.
25. **Whole Health AMSAs:**
26. Schedules Veterans into TCR Aspire Program based on RTCs.
27. Mails TCR Aspire packets (workbook, food logs, welcome letter/schedule, 2 resistance bands) 2 weeks prior to the 1st class.
28. **CACs (? Acronym):**
29. Build Note template in computerized medical record
30. **Print Shop:**
31. Upon request from MOVE! Coordinator prints workbooks and food logs for TCR Aspire.
32. **Clinical Care Team** (Primary Care Providers, Endocrine, Nephrology, Risk Reduction PharmD) Refer Veterans to TCR Aspire. Read TCR Aspire Discharge Note in order to be informed of changes that occurred during the program.
33. **\*\*\*Anti-Coagulant Clinic:** Acknowledge possible need for change to anti-coagulant medications during participation in TCR Aspire Program.

## DEFINITIONS? Do we have anything that needs defining?

**REFERENCES --- NEEDED:**VA/DoD guidelines?

Management of Diabetes Mellitus in Primary Care (2017) - VA/DoD Clinical Practice Guidelines. Accessed September 6, 2022.

ADA Guidelines?

1. Committee ADAPP. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: Standards of Medical Care in Diabetes—2022. *Diabetes Care*. 2022;45(Supplement\_1):S60-S82. doi:10.2337/DC22-S005

## REVIEW

Review is at minimum at recertification, when there are changes to the governing document and any regulatory requirement for more frequent review.

## RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of August 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

## SIGNATORY AUTHORITY

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*Dr. Elizabeth Lima*

*Chief of Whole Health Department*

Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***NOTE:*** *The signature remains valid until rescinded by an appropriate administrative action.*

**DISTRIBUTION:** SOPs are available at:

**Attachments:**