Medical Program Task Force Recommendations

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Tracking of Annual Review & Approval of Medical Program Task Recommendations

Review Year	Complete	Approved	Released
2015	February 2015	February 27, 2015 – OBN Advisory Board	March 25, 2015
2016			
2017			
2018			
2019			
2020			

1. Hospital Medical Program Eligibility

The current Medical Program is under a formal program evaluation. Until such a time that the evaluation results are analyzed and community capacity is determined, the Medical Program Task Force is not recommending a change to the current Medical Program eligibility criteria.

The current eligibility criteria (as directed by the OBN in April 2013) is as follows:

18 years of age and older (Note: The program does not discriminate by age, if a patient is ≥65 years of age, sites may consider eligibility on a case by case basis)

- BMI ≥ 35
- BMI ≥ 30 and one of the following:
    - Idiopathic Intracranial Hypertension
    - Complicated Type II Diabetes Mellitus
    - Poorly Controlled Hypertension
- Also
    - Out of country/out of province surgical patients (funded by the MOHLTC) with complications, i.e. requiring post-op care
    - Out of country/out of province surgical patients (funded and not funded by MOHLTC) with weight related issues, i.e. weight regain

Exclusion Criteria:

- Current drug or alcohol dependency (within 6 months of referral)
- Recent major cancer (life threatening, within last 2 years) with active treatment where caloric restriction might exacerbate the condition
- Untreated or inadequately treated psychiatric illness

Exclusion Decision at Site Level:

- Major surgery booked to take place during the program
- Patient undergoing active cancer treatment
- Patients with the potential for fluid and electrolyte issues (e.g. renal and cardiac failure)
- Patients who cannot make a commitment to a full program

- Patients deemed unable to comprehend or comply with diet and counseling

2. Definition of a Medical Program Case

Medical Program cases are counted once the formal treatment plan has commenced. This would be the time the patient starts group intervention for the meal replacement program, lifestyle program, or 1-1 intervention.

Note: Group Sessions are closed groups so once programming starts, there is no capacity to place another patient into that spot.

3. Program Funding

MOHLTC funding is a one-time amount per patient for the full 2 year program. Funding amount includes patient care, lab work costs, and data collection, including data entry into Bariatric Registry.

4. Medical Program Attendance

Each site must demonstrate that patients have been informed that attendance is mandatory with the exception of illness, planned vacation, or extenuating circumstances. Patients should be assessed at intake to determine if they are committed to making the necessary investment in the Medical Program.

If a patient misses a scheduled intervention or group class, opportunities for patients to meet with team members (i.e. Registered Dietician, Social Work, Registered Nurse) to review missed session content is encouraged. These follow up counselling opportunities can be arranged by phone or in person.

5. Types of Medical Programs

The programs that can be provided under the Medical Program funding envelope include:

a) Lifestyle/Behavioral Modification Program

b) Meal Replacement/Behavioral Modification Program

c) One to One Program

6. Centre Requirements to Administer Hospital Medical Programs

- Case Management by Physician or NP (with access to physicians for consultation)

- Registered Dietician
- Master's Prepared Social Worker, Behaviorist, or Psychologist
- Kinesiologist, Exercise Physiologist, Physiotherapist, or Occupational Therapist
- Access to Pharmacotherapy (as required)

7. Focus of Medical Programs

For all Medical Programs, the focus is to help patients achieve medically acceptable weight loss in order to improve their co-morbidities and quality of life. The programs focus on helping patients achieve a healthier state of wellness by providing knowledge and life skills to change their eating and coping behaviors, and develop alternative lifestyles that promote healthy eating, physical activity, and healthy living.

The program is not designed to help patients achieve a desired GOAL weight. The program is time limited and not intended to provide ongoing intervention for an extended period of time or provide active treatment to assist patients to achieve a target weight. Patients cannot repeat the medical program. The program is a one-time only MOHLTC funded program per patient providing intervention for 2 years.

8. Directives for the Medical Program

a) The Medical Program is a 2 year commitment for patients.

b) Treatment completion is defined as completion of the active phase of a patient's program (duration of 6 months for all programs).

c) Patients are enrolled for 6 months of maintenance (following the active phase of their program) and 12 months of monitoring (between years 1 and 2).

d) Patients cannot be referred or switch to the Surgical Program until the active phase and maintenance phase of their program is complete = 12 months.

e) Patients can transfer to the Surgical Program prior to treatment commencement (start of their active phase).

f) The Medical Program is not intended for weight reduction for patients intending to proceed with bariatric surgery. It is not a bridging program to surgery.

g) Patients who require significant weight reduction as requested by a bariatric surgeon prior to commencing with surgery is not considered a Medical Program patient. These patients should be seen 1-1 and considered part of the pre/post funding for the Surgical Program.

h) Patients cannot repeat the Medical Program, it is a one-time only MOHLTC funded program per patient.

i) Patients who have participated in the full 2 year Medical Program and have weight regain issues must seek alternative services or treatment modalities.

j) Patients cannot participate in a meal replacement program and then be referred to another Medical Program (i.e. Lifestyle program).

k) Patients should be transitioned to back to the community (i.e. Primary Care Provider) at the end of the 2 year program.

9. Medical Program Standardization (Minimal Requirements)

a) Orientation

For all programs, it is a requirement that patients attend a formal orientation session upon referral to the Medical Program. This patient information session includes both a clinic and program overview along with patient accountabilities.

b) First Medical Appointment

For all programs, it is a requirement that patients are booked for an initial medical assessment by physician or NP to discuss personal medical information, health history, and other relevant information to determine candidacy to the program.

c) Mandatory Diagnostic Testing and Blood Work

For all programs, there is no mandatory diagnostic testing for patients except for blood work as indicated in Appendix (approved by OBN Medical Task Force & OBN Advisory Board February 2015).

During the first medical appointment, based on a patient's medical history, diagnostic tests may be ordered at the discretion of the physician/nurse practitioner.

d) Follow up Patient Assessment

For all programs, prior to treatment commencement, a follow up patient appointment is required to review lab results and any diagnostic investigations ordered to reconfirm candidacy to the program and ensure they are appropriate for treatment intervention.

e) Medical Supervision

All Medical Program patients must be evaluated at treatment completion (approx. 6 months), 1 year, and 2 years after treatment completion.

Meal replacement program patients, following commencement of their treatment plan, are to be followed every 2 to 4 weeks or more frequently at the discretion of the physician or NP, depending upon the medical requirements of the patient.

Behavioral modification program patients, following commencement of their treatment plan, may be evaluated and followed according to their clinical indications or medical requirements.

f) Medical Programs

NOTE: New Directive for Fiscal 2015/2016 Implementation: For the Lifestyle/Behavioral Modification Program, the evidence suggests that for optimal outcomes, active treatment should run for at least a 6 month period with a minimum of 14 visits during the treatment phase (Obesity, 2014). The current Lifestyle program is to shift to providing a 26 week program with thirteen (13) bi-weekly group sessions, allowing the active phase of treatment to be more in alignment with the recommended guidelines and making treatment 6 months in duration for all Medical Programs.

All Medical Programs are two years in duration with 3 phases:

a. Active Phase of Program (Treatment Plan = 6 months)
    i. 26 weeks for lifestyle/behavioral modification
    ii. 26 weeks for meal replacement/behavioral modification
    iii. 26 week for 1-1 patients

b. Maintenance Phase of Program – Once the active phase of the treatment plan is complete, this maintenance phase (6 months in duration) provides support to the patient up to the first year.

    The goal of this phase is weight maintenance. Wing and Hill (2001) propose that successful weight loss maintainers be defined as "individuals who have intentionally lost at least 10% of their body weight and kept it off at least one year." Weight maintenance = <3% change in body weight (Donnelly, 2009)

    During this phase, at the discretion of the bariatric center, regular support programs (1:1 and group sessions) should be offered at a minimum of once per month (face to face) along with counselling as indicated to ensure patients are successful in maintaining their weight loss.

    Patients may continue to lose weight during the phase through healthy lifestyle changes. This is supported and encouraged but no active weight loss treatment intervention should be offered during this phase.

    Patients who experience weight regain during the maintenance phase, may be offered 1:1 intervention only using a tool box" approach that includes:

i. Partial meal replacement
ii. Pharmacotherapy
iii. Individual sessions with appropriate health care professional

There is no accepted definition of weight regain after weight loss. Estimates vary between 10-30% of weight lost (Karmali et al, 2013). For the purposes of this program, it is suggested that a gain of 30% of maximum weight lost be used as a measure to determine 1:1 patient intervention during this phase.

c. Consolidation Phase of Program – Once the maintenance phase of the program is complete, the next 12 months (between Year 1 and Year 2 of the program) is focused on providing ongoing support to patients to ensure sustained results through didactic learning.

It is suggested that a minimum of 4-6 didactic sessions are implemented for patients to complete online over the course of the year. Patients would then be booked for a follow up appointment at 24 months for final blood work and data collection on patient outcomes. Note: OBN is looking at the development of these sessions provincially.

No active intervention should be initiated during this phase (i.e. no pharmacotherapy or meal replacement or 1:1 intervention).

10. Specific Features of each Medical Program Treatment Plan

Meal Replacement/Behavioral Modification Treatment Plan (6 months)

Patients participate in a 26 week formal group treatment plan led by an interdisciplinary team which includes weekly clinic visits and group sessions (approximately 2-3 hours in duration) focused on weight loss with meal replacement.

- Week 1 = Preparation for meal replacement
- Week 2-13 = Low calorie meal replacement (4 meal replacement shakes per day = 900 kcals per day) and education
- Week 14-20 = Progressive re-introduction of food and education
- Week 21-26 = On-going support and education

Lifestyle/Behavioral Modification Treatment Plan (6 months)

Patients participate in a 26 week behaviour modification treatment plan led by the interdisciplinary team with 13 bi-weekly clinic visits and group sessions approximately 1.5-2 hours in duration, focused on weight loss without meal replacement. These sessions are typically shorter than our meal replacement groups because they don't have to be seen by an NP or physician routinely.

One to One Treatment Plan (6 months)

Patients participate in a 1-1 monitoring, education and support plan for 26 weeks focused on weight loss with or without meal replacement. If meal replacement is part of the treatment plan, the following guidelines should be followed:

- 1-2 meals incorporated with meal replacements each day (2-3 Optifast or alternate product per day can be used)
- 1000-1200 kcals/day meal replacements with food

Individualized patient visits occur every 2-4 weeks and include visits with the physician or NP, along with visits with appropriate team members i.e. Social Worker, Registered Dietician. The program is intended for patients unable to participate in a group format.

Please note the 1:1 program also provides intervention and services to:

- Out of country/out of province surgical patients (funded by the MOHLTC) with complications, i.e. patient requiring post-op care
- Out of country/out of province surgical patients (funded and not funded by MOHLTC) with weight related issues, i.e. patient experiencing weight regain that are not appropriate for group intervention

11. Monitoring of Medical Program Patients

It is recommended that all patients participating in Medical Programs be followed for a period of 2 years with key points of assessment, evaluation and data collection at the following intervals:

- Baseline/Initial Assessment
- Treatment Completion (Active Phase of Treatment Plan = 6 months)
- 1 year
- 2 year

12. Data Collection for Medical Program Evaluation

Note: these measures would be collected in the Medical Program Bariatric Registry.

a) Weight loss (% of loss from baseline)

b) Weight maintenance (% of weight maintenance – presenting weight at 2 years)

c) Improvement in Comorbidities specifically:
   i. Diabetes

ii. Hypertension – Improvement in diastolic and systolic measures
iii. Dyslipidemia
iv. OSA
v. Others as indicated in Bariatric Registry Case Report Forms

d) Improvement in Medications/Treatment – specifically:
   i. Anti- Hypertensive
   ii. Anti – Diabetic
   iii. Analgesic/Narcotic
   iv. Anti-Inflammatory
   v. Anti-Depressant
   vi. Lipid Lowering
   vii. CPAP

e) Improvement in Lab Values – specifically:
   i. Fasting Blood Glucose
   ii. Fasting A1C
   iii. Fasting ALT
   iv. Fasting Cr
   v. Fasting Total Cholesterol
   vi. Fasting TG
   vii. Fasting HDL
   viii. Fasting LDL

f) Improvement in Quality of Life – Recommendation to use Euroqol to be completed at:
   - Baseline/Initial Assessment
   - Treatment Completion (Active Phase of Treatment Plan = 6 months)
   - 1 year
   - 2 year

g) Level of Patient Satisfaction – Standardized OBN provincial tool to be implemented at all sites to be completed at:
   - Treatment Completion (Active Phase of Treatment Plan = 6 months)
   - 1 year
   - 2 year

References

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Appendix

Medical Program Patient Blood Work

Minimum Clinical Requirements (Fasting 12 hours)

Laboratory Investigation	Baseline	Treatment Completion (approx. 6 months)	12 months	24 months	*Additional Lab work for Meal Replacement Program Patients
FBS	yes	yes	yes	yes	as needed
A1c	yes	yes	yes	yes	
ALT	yes	yes	yes	yes	
Creatinine	yes	yes	yes	yes	yes
Total Chol	yes	yes	yes	yes	
TG	yes	yes	yes	yes	
HDL	yes	yes	yes	yes	
LDL	yes	yes	yes	yes	
CBC	yes	no	no	no	
AST	yes	as needed	as needed	as needed	
NA	yes	as needed	as needed	as needed	yes
K	yes	as needed	as needed	as needed	yes
HCO3	yes	as needed	as needed	as needed	yes
Urea	yes	as needed	as needed	as needed	yes
Uric acid	yes	as needed	as needed	as needed	
TSH	yes	as needed	as needed	as needed	
Urine Microalbumin for diabetics and hypertensive patients only	yes	as needed	as needed	as needed	

*** As indicated above, for <u>ALL PATIENTS ON MEAL REPLACEMENT,</u> the additional lab work indicated is to be obtained at 1 month post treatment commencement and then monthly as clinically indicated above, especially for patients who are volume sensitive (such as patients with congestive heart failure, renal dysfunction, or patients taking diuretics, ACE inhibitors, or ARBs).**

Note: for MEAL REPLACEMENT PATIENTS ON COUMADIN, communication should be established with the patient and physician who is monitoring the INR. At least weekly INRs (or more often, as clinically indicated) should be obtained while on meal replacement, as INRs can increase dramatically while patients are on Meal Replacement Supplements.

Note: The laboratory investigations highlighted above are collected and recorded at the key time intervals and noted within the Bariatric Medical Registry.