• What is it?
  ✓ Behavioral lifestyle program.
  ✓ 104 week program consisting of Physician/Provider and Dietitian visits.
  ✓ Very-low calorie diet followed by transition to balanced, individualized low calorie meal plans.
  ✓ Focus on long-term sustainable weight maintenance.

• Who may be eligible?
  ✓ Adults between 20 – 70* years old
  ✓ Body Mass Index (BMI) 30 to 50 kg/m²**
  **Asian/Asian-Indian with BMI between 27 to 50 kg/m²

• Which insurers cover the program?
  ✓ Blue Care Network (BCN)
  ✓ Blue Cross Blue Shield of Michigan (BCBSM)
  ✓ Health Alliance Plan (HAP)
  ✓ Priority Health
  ✓ Commercial (other): patient would be provided with billing codes to check with the insurer

*Medicare does NOT cover the program
WEIGHT MANAGEMENT PROGRAM — Brief Overview

**Start:**
Orientation & Paperwork

**Scheduling**

**Provider Visit:**
- Medical history
- Discussion
- Labs

**Research**
*Optional*

**Dietitian visit:**
Start the Diet

**Maintenance Phase**

**Program Completion**
- 104 weeks, total

**Very-Low Calorie Diet Phase**
- Weekly visits x 1 month
- Monthly visits, thereafter

**Low Calorie Diet Phase**

**Research**
Want to know some **STATISTICS** about **OBESITY**?

Check out **Appendix (A)**
We think it is important to know some of the FACTS about OBESITY.
Energy Balance: What Determines Weight?

Energy Intake
Ingestion of:
• Protein
• Fat
• Carbohydrate

Energy Expenditure (EE)
• Physical Activity (exercise)
• Diet-Induced Thermogenesis (energy needed to break down and metabolize food)
• Basal Metabolic Rate (energy burned while at rest and the biggest contributor to EE)

Body weight is determined by the balance between the calories we **consume** and the calories we **expend** (aka: “burn”).
OBESITY HEALTH RISKS:

What are the consequences of too much weight? Overnutrition leads to a number of metabolic problems that lead to diseases such as diabetes and heart disease.

- Heart disease
- Stroke
- Diabetes
- Kidney disease
- Blood clots

- Breathing problems
- Cancer
- Pregnancy complications
- Fatty liver disease
- Premature death
Want to have a better understanding of the DISEASE of obesity?

Check out Appendix (B)
PROGRAM GOAL: Identify strategies that will result in long-term weight management for individuals with obesity, using the latest research and clinical strategies.

We are committed to educating, motivating, and empowering individuals to make healthy lifestyle choices!
PERSONALIZED PROGRAM:
Multidisciplinary approach to weight loss and weight maintenance

Structured and organized into different phases:
- Initial: very low calorie diet
- Transition: low calorie diet
- Maintenance: individualized diet plan

Services: one-on-one sessions that provide...
- Medical guidance
- Advice regarding activity/exercise/conditioning
- Strategies for prevention of weight regain:
  - Behavioral
  - Nutritional
  - Pharmacological
Stepped Obesity Treatment Regimen

What happens at the FIRST VISIT to the physician/provider?

• Your health and weight history is obtained.
• Your current medication list is reviewed.
• Blood work (aka: labs) are performed.
• The research is discussed and your consent to participate is obtained (if you are interested).
ADJUST medication regimen

- Minimize ‘weight positive’ medications
- Substitute with weight neutral or weight negative medications
PROVIDE Exercise “prescription”

- Recommendations will be customized based on **health status**.
- **Standard:** work up to 40-60 minutes of exercise/enhanced activity per day.
- **Initial** phase: **low** intensity activity
- **Maintenance** phase: **moderate** intensity activity
INITIATE caloric restriction

- Initial **very-low**-calorie diet (VLCD) (800 cals/day) or **low**-calorie-diet (LCD) (1000-1200 cals/day):
  - Meal substitution/replacement
  - Dietary counseling: One-on-one with registered dietitian (RD)
  - Initial emphasis on calories and caloric density, not fuel

The meal replacement diet will not start until you meet formally with the program’s dietitian.
WEIGHT MANAGEMENT PROGRAM

VERY-LOW Calorie Diet (VLCD) Phase

- Duration: 8-12 weeks*
- Caloric intake: typically 800 calories/day*
- Product(s):
  - Optifast® 800 Shakes (or Ready-to-Drink shakes)
  - Optifast® soups
  - Optifast® Bars (not used, initially)
- Details: will be explained by the dietitian.
- Average diet: typically 4-5 shakes + 1 soup

*Variable: as determined by your provider

The meal replacement diet will not start until you meet formally with the program’s dietitian.
WEIGHT MANAGEMENT PROGRAM

WHY use a VERY-LOW Calorie Diet (VLCD)?

• Research on diets using VLCD shows that it is an effective tool both for weight loss and maintenance of a reduced weight.
• It is intended to be a tool that is meant to be used on an intentional basis for a limited amount of time.
• It is a tool that can help the participant separate him/herself from unhealthy food habits by making meals “decision-free.”
• While on the VLCD, there is time to learn nutrition information and start practicing lifestyle and behavioral skills.
WHEN is a VERY-LOW Calorie Diet (VLCD) used?

- Full meal replacement/ VLCD is appropriate for individuals who have a significant amount of weight to lose
- AND-
- Past efforts to cut-back on food or follow a reduced calorie meal plan have not resulted in weight loss
- OR-
- Past diet efforts have resulted in weight LOSS but the reduced weight could not be SUSTAINED.
WHAT amount of weight loss should be expected on the VERY-LOW Calorie Diet (VLCD)?

• Every individual is DIFFERENT!
• In general, the following would be reasonable expectations:
  • After 1-4 weeks: a weight loss of 3-7%
  • After 5-8 weeks: a weight loss of 5-14%
  • After 9-12 weeks: a weight loss of 11-22%
    WITH AVERAGE = 15%
CAN individuals with DIABETES use a VERY-LOW Calorie Diet (VLCD)?

• YES! Optifast® is recommended by physicians for their patients with diabetes because of the foods' nutritional formulation and low calories.

• Your medication(s) will be monitored by our physicians/providers and dosage may change throughout the program.
CAN individuals with FOOD ALLERGIES use OPTIFAST®?

• Optifast® products are generally well tolerated by most people.

• Optifast® POWDERED shake mix (chocolate, vanilla, and strawberry) DO contain SMALL amounts of lactose. All other products are lactose-free.

• Some of our products, however, contain common allergens such as DAIRY, EGGS, WHEAT, SOY AND PEANUTS.

• Please let us know if you have any allergies prior to beginning the shake regime, or if any GI discomfort occurs.
WHAT is the COST of OPTIFAST®?

- You are responsible for purchasing the product (~$2.60 per shake or ~$13-15/day). Insurance does NOT cover the cost of meal replacements.

- Of note: The average American spends $140/week on food according to the US Bureau of Labor Statistics Consumer Expenditure Survey.
HOW does the COST of OPTIFAST® compare to fast food purchases?

Source: Citi Research, NPD Crest, FRSH Investor Presentation, Blaze Investor Presentation
HOW does the COST of OPTIFAST® compare to other weight management programs?

- The costs of our program are comparable to/competitive with many major commercial weight programs.
Want to learn more about the RESEARCH DATA surrounding MEAL REPLACEMENT?

Check out Appendix (C)
LOW Calorie Diet (LCD) Phase

- Initiation: following ~15% weight loss, “conventional” food is gradually reintroduced. This is tailored to your needs & preferences.
- Duration: Variable.
- Purpose: transition from full meal replacement back to convention food in a STRUCTURED way.
Weight MAINTENANCE Phase

- Duration: Entire rest of the program
- Purpose: Maintain the REDUCED WEIGHT STATE
- Methods:
  - Dietary counseling/education
  - Behavioral techniques
  - In appropriate situations, the following may be considered:
    - Referral to a therapist
    - Use of weight control medication(s)
What **RESULTS** have been attained by participants?

**Weight Maintenance by Sex**

- **Male**
  - Baseline: 129 kg
  - Week 2: 125 kg
  - Week 4: 120 kg
  - Week 8: 114 kg
  - Week 12: 110 kg
  - Week 18: 106 kg
  - Week 24: 106 kg
  - Week 28: 103 kg
  - Week 32: 103 kg
  - Week 36: 103 kg
  - Week 40: 103 kg
  - Week 44: 103 kg
  - Week 48: 103 kg
  - Week 52: 103 kg
  - Week 56: 103 kg
  - Week 60: 103 kg

- **Female**
  - Baseline: 111 kg
  - Week 2: 107 kg
  - Week 4: 104 kg
  - Week 8: 100 kg
  - Week 12: 97 kg
  - Week 18: 94 kg
  - Week 24: 92 kg
  - Week 28: 90 kg
  - Week 32: 90 kg
  - Week 36: 90 kg
  - Week 40: 90 kg
  - Week 44: 90 kg
  - Week 48: 90 kg
  - Week 52: 90 kg
  - Week 56: 90 kg
  - Week 60: 90 kg
What **RESULTS** have been attained by participants with **DIABETES**?

**Effect on Diabetes (study n=58)**

- **A1c UNDER 7%**
  - Baseline: 40%
  - Follow-up: 76%

- **A1c OVER 7%**
  - Baseline: 60%
  - Follow-up: 24%

- **Sixty percent** of patients with established diabetes had baseline HbA1c over 7.0%.

- At **follow-up**, 76% of patients had HbA1c UNDER 7.0%.

- At **follow-up**, 100% of patients with newly diagnosed diabetes and 76% of patients with established diabetes had HbA1c UNDER 7.0%.

- At **follow-up**, 57% of patients were on ≤ 1 diabetes medication(s).
WEIGHT MANAGEMENT PROGRAM

RESEARCH PROGRAM COMPONENT

- Research programs are offered by the UNIVERSITY OF MICHIGAN
- Research is separate from the clinical program, but can be helpful to add important information to help you manage your health
- Participation is voluntary
RESEARCH COMPONENT: “PHENOTYPING”

• WHAT IS IT? It is an examination of gene-gene interactions and gene-environmental interactions for the purposes of understanding the biology of weight regulation

• WHY DO IT? This better understanding may help us identify the factors that predict success for weight loss and maintenance of weight loss. Furthermore, this may be the key to changing our treatment paradigms so that they become even more individualized and even more effective
  ▪ We believe that the research is integral to the understanding of obesity
  ▪ It may also lead to finding/examining potential novel therapeutic targets

• MUST I DO IT? NO - Participation is VOLUNTARY
RESEARCH COMPONENT: “PHENOTYPING”

WHEN DO I GO FOR TESTING?

- **INITIAL TESTING:** after seeing the physician/provider but BEFORE starting the diet.
- **INTERIM:** after you achieve a certain degree of weight loss (typically 10-15%)
- **FINAL:** At the END of the program
Oral Glucose Tolerance Test (OGTT): 2 hour test to diagnose diabetes*. 

Fat and muscle biopsies

Body composition by DEXA or BodPod.

Questionnaires regarding overall health and impact of weight on emotional and physical well-being

Resting Energy Expenditure and Exercise Capacity (REE, V02 max)

*NOTE: ~1/3rd of the participants in the program have Type 2 diabetes mellitus and many were undiagnosed prior to OGTT.
WHAT will be done with the RESEARCH information?

- If you participate in research, information and data that is relevant to your care will be shared with you and your primary physician/provider. This information includes your resting energy expenditure, your V02 max (aka: exercise capacity/level of fitness), your body composition data from DEXA, and your oral glucose tolerance test results.

- This information is NOT shared with your insurance company.
Want to learn more about the different RESEARCH COMPONENTS?

Check out Appendix (D)
PROGRAM WEBSITE

- http://www.uofmhealth.org/conditions-treatments/adult-weight-management

- Please fill out “INITIAL EVALUATION FORM” and all the QUESTIONNAIRES BEFORE your first physician visit. Remember to BRING these with you to your first appointment. You may also email them to wmpconnection@med.umich.edu.
  - You will complete the questionnaires again following ~15% weight loss and at the end of the 2 year program.
QUESTIONS/CONCERNS?

Need to set up your first visit? Please call: 734-647-5871 and speak with Rachel Brown

For research opportunities:

- Nicole Miller, MPH, RD: npiazza@med.umich.edu

Need to set up your first visit? Please call: 734-647-5871 and speak with Rachel Brown
PUBLICATIONS

• The Impact of weight loss on health-related quality of life
  • www.ncbi.nlm.nih.gov/pubmed/24129672
• The impact of a managed care obesity intervention on clinical outcomes and costs: A prospective observational study
• Very-low-energy diet for type 2 diabetes: An underutilized therapy?
  • www.ncbi.nlm.nih.gov/pubmed/24849710
• Effect of Total Meal Replacement Program Compared with Reduced-energy Food-Based Diet Plan on Glycemic Status-Results from the OPTIWIN Study
  • https://diabetes.diabetesjournals.org/content/67/Supplement_1/298-L