

# Basic Health Insurance Policy

## Allied Cooperative Insurance Group (ACIG) S.J.S.C

Paid Capital 291 Million Saudi Riyals – C.R. 1010417178 R.C.C. 95957  
H.O. Riyadh P.O. Box 40523. Riyadh 11511 Kingdom of Saudi Arabia  
Tel.: +966 11 485 2626 Fax: +966 11 489 0555  
Jeddah C.R. 4030171999 Tel.: +966 12 663 3222 Fax: +966 12 661 7421  
Al Khobar C.R. 2051043671 Tel.: +966 13 893 3637 Fax: +966 13 893 8440  
Khamis Mushayt C.R. 5855035150 Tel.: +966 17 221 5521 Fax: +966 17 223 7465  
Saudi Central Bank Product ID # A-ACIG-2-C-13-037

## المجموعة المتحدة للتأمين التعاوني ( أسيج ) ش.م.س

رأس المال المدفوع 291 مليون ريال سعودي – س.ت 1010417178 ع.غ.ت 95957  
المركز الرئيسي الرياض ص.ب 40523 الرياض 11511 المملكة العربية السعودية  
ت: +966 11 485 2626 ف: +966 11 489 0555  
جدة س.ت 4030171999 ت: +966 12 663 3222 ف: +966 12 661 7421  
الخبير س.ت 2051043671 ت: +966 13 893 3637 ف: +966 13 893 8440  
خميس مشيط س.ت 5855035150 ت: +966 17 221 5521 ف: +966 17 223 7465  
الرقم التعريفي للمنتج في البنك المركزي السعودي A-ACIG-2-C-13-037

## Basic health insurance policy

Subject	Page
Contents	1
<a href="#">Health Insurance Policy objectives</a>	3
<a href="#">Chapter One — Definitions</a>	4
<a href="#">Chapter Two - Recoverable Expenses/Benefits</a>	13
<a href="#">Chapter Three - Controls and Exceptions</a>	15
<a href="#">Chapter Four - General Conditions</a>	19
<a href="#">Chapter Five- Insurance Drug formulary (IDF)</a>	33
<a href="#">Chapter Six- Provider Network</a>	37
<a href="#">Chapter Seven- Health Benefits Schedule (1)</a>	43
<a href="#">Chapter Eight- Basic Health Insurance Policy Schedule (2)</a>	48
<a href="#">Chapter Nine- Policy Appendix</a>	53
<a href="#">Chapter Ten- Guidance Suggested Benefits</a>	64

## Key Objectives of Health Insurance Policy

The following Health Insurance policy is developed to target seven key objectives based on the vision of the Council to be an international leader in promoting preventive therapy and enhancing the quality and efficiency of health care services for health insurance beneficiaries.



# Chapter One

## Definitions

The terms and expressions mentioned herein shall have the meanings ascribed thereto, and expressions that are not defined herein shall have the same meanings ascribed thereto in the Law or the Implementing Regulations:

1. **Kingdom:** Kingdom of Saudi Arabia
2. **Council:** The Council of Cooperative Health Insurance and its General Secretariat.
3. **Law:** The Cooperative Health Insurance Law applied in the Kingdom.
4. **Executive regulations:** Executive bylaw Regulation.
5. **Policy:** This basic health insurance policy, including its schedule, appendices, and annexes.
6. **Health insurance:** Health insurance is established by the Law and its implementing regulation under this policy, with its schedule, appendices, or annexes and it is practiced by cooperative insurance companies licensed to operate in the Kingdom under the Insurance Companies Control Law.
7. **Health insurance term:** The period indicated in the policy schedule for which health insurance remains valid.
8. **Effective period:** The number of days during which the policy will be effective if the full subscription indicated in the policy schedule is not paid.
9. **Start date:** The date indicated in the policy schedule at which insurance coverage begins.
10. **Effective date:** The date on which a person becomes eligible for coverage under this policy or to add or delete an insured person in the policy.
11. **Benefit:** Cost of providing healthcare services included in the insurance coverage within the limits indicated in the policy schedule
12. **Insurance coverage:** Basic health benefits available to the beneficiary as specified in the policy
13. **Coverage limits:** The maximum liability of the insurance company as specified in the policy schedule for any insured person before applying the deductible.
14. **Insurance parties:** Insurance Company, brokerage firm, service providers, revenue cycle Management Company, third-party administrators (TPAs), policyholder, beneficiary and anyone considered a party to the insurance parties under the Executive Regulations.

15. **Insurance company:** A cooperative insurance company licensed by SAMA to operate in the Kingdom and accredited by the CHI to provide cooperative health insurance.
16. **Policy Holder:** A natural or corporate person in whose name the policy is issued
17. **Beneficiary or insured:** A natural person (or persons) to whom coverage is provided under the policy.
18. **Employer:** A natural or corporate person employing one or more employees
19. **Employee:** Every natural person working for and under the management and supervision of an employer in return for a wage, even if the employee is not under his immediate supervision
20. **Dependent(s):** Husband or wife, sons up to the age of twenty-five and unmarried daughters in addition to orphans fostered by foster families, receiving compulsory health insurance.
21. **Service provider:** healthcare facilities (governmental/non-governmental) licensed to provide healthcare services in the Kingdom under relevant laws and rules approved by the Council, such as hospitals, general, and specialized medical complexes, diagnostic centers, clinics, pharmacies, laboratories, physiotherapy, or radiotherapy centers.
22. **Preferred Provider Network (PPN):** A group of healthcare service providers approved by the CHI and specified by the insurance company to provide healthcare services to the insured. These services are directly credited to the insurance company's account. This network includes the following levels of health services:
  - Level 1 (primary health care).
  - Level 2 (public hospitals).
  - Level 3 (specialized or reference hospitals).
  - Other complementary health service provider centers (such as One-day surgery centers, pharmacies, physiotherapy centers, eyeglasses shops, Telemedicine, Home health care).
23. **A hospital:** A health facility approved by the CHI, accepted by the policyholder and the insurance company, and licensed to work as a hospital under the regulations to provide health services for which compensation may be claimed under this policy.
24. **Licensed doctor:** Practicing the medical profession with the appropriate scientific qualification according to the classification of the Saudi Commission for Health

Specialties (SCFHS) and is licensed to practice the medical profession by the Ministry of Health.

25. **Primary care:** Health services provided by medical teams under the supervision of qualified practitioners so that these services are comprehensive, continuous, coordinated and based on Value-Based Healthcare. Primary care ranges from counseling and prevention to treatment of organic and psychological diseases for all ages and categories of beneficiaries, maternity care and child health services, rehabilitation, palliative care, urgent care services, chronic disease care, population health and others as needed to serve beneficiaries registered with primary care providers and under approved medical best practices.
26. **Disease:** Illness or conditions that affects the insured person and necessarily requires medical treatment from a licensed doctor before and during the period of health insurance.
27. **Accident:** The sudden and unexpected, unforeseen, occurrence physical event during the health insurance period.
28. **Traffic accident:** Any accident that results in serious or light damage or partial or total material loss to property inadvertently due to the use of the vehicle while in
29. motion. **Vehicle:** Every means of transport on wheels or track, and are driven or carried by automatic or animal force, including any mechanical or electric vehicle, whether it is a
30. **Employment "occupational" injury:** Any accident suffered by the beneficiary during performance or because of his work. or on his way from his dwelling to his workplace and back, or on his way from his workplace to the place where he usually takes his meal or gives his prayer and back. or a the disease established to be caused by work. The occupational disease duly determined in accordance with the occupational diseases schedule, taking into account the date of the first medical diagnosis of the disease is regarded as the date on which the injury is sustained.
31. **Personal risks:** Any act or practice performed by a person is recognized as a risky activity if it carries a risk of illness or accident or is expected to cause complications of a previous illness or injury that are a result of actions not associated with the work of the insured or regular daily practices such as: dangerous sports (judo, boxing, karate, wrestling, combat sports), motor, boat and motorcycles racing, paragliding, parachuting.

32. **Emergency:** Urgent medical treatment required by the medical condition of the insured as a result of an accident or a case requiring prompt medical attention, depending on the following levels of urgent medical care (1. Resuscitation, 2. Emergency, 3. Urgent condition that may be resulting in death, loss of one or more organs, or the occurrence of an accidental or permanent disability situation) as described by the Private Health Institutions Law and Regulations approved by the Ministry of Health, which determines how to dispatch emergency cases.
33. **Outpatient treatment:** The beneficiary visits outpatient clinics for diagnosis or medical treatment.
34. **Day care surgery or treatment:** A patient admitted during the course of a day with the intention of receiving care who does not require the use of a hospital bed overnight and who returns home as scheduled. It should be noted that their coding and pricing is in accordance with the hospital's procedure for admission
35. **Inpatient (hospital admission):** Registration of the insured person as a patient for admission in the hospital until at least the next morning, including a Patient admitted with this intention who leaves hospital for any reason without staying overnight
36. **Long-term care:** A variety of services that include medical and non-medical care provided to people who are unable to perform activities essential to daily living for people suffering from a chronic illness or disability, or cannot care for themselves for long periods. long-term care focuses on individual and coordinated services that promote independence, improve patients' quality of life, and meet patients' needs over a long period.
37. **Telemedicine:** Using electronic information and communication technology means to provide diagnostic, screening, and medical inspection services to the patient, including, for example, telemedicine and health using smartphones (Health Mobile). Other forms telemedicine includes (teleconsultation, tele-expert consultation, remote assistance, other medical opinions)
38. **Alternative medicine (complementary):** A variety of healthcare systems, practices and products that are not part or extension of modern medical practice. Complementary medicine is used in conjunction with modern medicine, while alternative medicine is not used with modern medicine at the same time. Examples include but are not the



limited to herbal treatment, cupping, Chinese medicine, hypnosis, osteopathy, chiropractic, acupuncture.

39. **Health:** A state of complete physical, mental and social health, not just lack of illness or disability.
40. **Allergies:** In particular, the individual is sensitive to certain types of food, medicine, weather, pollen or any other triggers from plants, insects, animals, minerals, elements or other substances. The individual experiences physical reactions caused by direct or indirect contact with those substances that cause conditions such as asthma, dyspepsia, friction, hay fever, eczema, and headache.
41. **Congenital Defect:** Functional, chemical or structural dysfunction that is usually present before birth, whether through heredity or as a result of environmental factors according to medical custom.
42. **Pregnancy and childbirth:** Any pregnancy or birth, including natural, cesarean and abortion.
43. **Preterm Baby:** a baby born before the 37th week of pregnancy (three weeks before the birthdate)
44. **Psychological cases:** A disorder of thinking, mood, perception, memory or mental abilities, some or all of them.
45. **Disability cases:** Disability means having a total or partial impairment permanently or for a long period of life in one of the physical, sensory, mental, communicative, educational or psychological abilities, and causes that the disabled person cannot meet the requirements of normal life and rely on others to meet them. Or the need for a special tool that requires training or special qualification for its proper use.
46. **Vision correction interventions:** Interventions to improve vision and have no effect to prevent vision loss such as LASIK , lenses and eyeglasses
47. **Functional vision correction interventions:** Interventions to improve vision that are important for vision preservation "avoiding vision loss". For example strabismus and Amblyopia procedures for children less than 14 years and keratoconus, cataract, glaucoma for all age groups.
48. **Human organ:** Any part of the human body (dead or alive), its tissues or any of its components, which can be used by transplanting them into another human body, except for blood.

49. **Transplant of Human Organs:** A medical operation through which the human organ is removed, or part of it, from the donor's body and implanted in the patient's body, by any medical and approved means.
50. **Rehabilitation:** An essential part of comprehensive health care and its applications to return a person suffering from an occasional or persistent weakness, failure, or defect to the best level of performance in their family and social life in line with the definition of health and the application of best approved medical practices.
51. **Essential Dental Procedures:** Any of the following medical procedures that include 1. Preventative services (dental consultations, annual examination of teeth and assessment of their problems, cleaning each beneficiary once a year (including fluoride), 2. Treating procedures include (fillings, periodontal treatment, teeth extract).
52. **Reconstructive surgery:** Reconstructive plastic surgery is performed to correct defects, abnormalities or injuries caused by an accident, infection, tumor or disease.
53. **Innovative "Brand" Name:** Preparations that contain a new active substance and are offered under a brand name on the market by the innovative company.
54. **Generic medication or treatment:** is a product equivalent to the innovative product in pharmaceutical form, concentration, method of administration, quality, effectiveness, and therapeutic claim.
55. **Premium (subscription):** Amount paid by the policyholder to the insurance company for the insurance coverage provided by the policy during the insurance term.
56. **Deductible (Co-payment):** Amount, if any, payable by the beneficiary upon receiving outpatient treatment as specified in the policy schedule, excluding emergencies and inpatient treatment.
57. **The basis of the direct entry or in company's account:** Facilities of non-payment appointed by the company and available for the insured. All expenses incurred at the facilities are directly debited from the company's account.
58. **Allowance compensation basis:** The method used to compensate the policyholder for the reimbursable expenses incurred by the insured and submitted a claim for them, after applying the deductible.
59. **Reimbursable Expenses:** Expenses paid in return for services, materials and equipment not excluded under Chapter 3 of this policy that is prescribed by a licensed physician due to the illness of the insured, provided such expenses are

necessary, reasonable, and normal in the relevant time and place based on best approved medical practices.

60. **Claim:** A request, accompanied by supporting financial and medical documents, submitted to the insurance company or representative thereof by the service provider, the insured or the policyholder for indemnification of expenses of healthcare services covered by the policy.
61. **Supporting documents for a claim:** All documents proving the insured's age, weight and height, nationality, identity, the validity of insurance coverage, the circumstances of the occurrence of the event resulting from that claim and proof of reimbursement of costs. It also includes other documents such as a police report, invoices, receipts, prescriptions, doctor's report, referral and recommendations, and any other relevant documents the insurance company may request.
62. **Fraud:** when any of the Insurance Parties performs or refrains from performing an act aimed at gaining an unfair or unlawful advantage for the benefit of the fraudster or other parties, or an act that involves fraud or deception that results from obtaining benefits or money, or providing benefits excluded or exceeding the permissible the limits to an individual or entity, and the like, according to the Law and Regulations.
63. **Abuse:** Practices by any insurance party which may lead to obtaining benefits or privileges they are not eligible to receive; without the intent to defraud, deceive, misrepresent, or distort facts to obtain such benefits and privileges and what comes under it under the Implementing Regulations, for example but Not limited to - exaggerating diagnostic tests and medications.
64. **Negligence:** Providing insurance/medical procedures without exercising the duly recognized reasonable amount of medical or insurance precautions that result in material or moral harm to one of the insurance parties, and which would not have occurred but for how the negligent person who acted.
65. **Age calculation:** Process by which age is calculated according to the calendar year starting at the beginning of January and ending at the end of December.
66. **Personal data protection system:** The Personal Data Protection Regulations issued by Royal Decree No. (M/19) dated 9/2/1443 H (16/9/2021)

# Chapter Two

## Recoverable Expenses / Benefits

For purposes of this policy, recoverable expenses shall mean the actual expenses incurred for services, supplies and equipment, which are not excluded under Chapter Three (3) herein, provided that it shall be prescribed by a licensed physician as a result of an illness suffered by the insured. Said expenses shall be necessary, reasonable and customary in the relevant time and place. Recoverable expenses shall include:


- (1) Costs of preparation and repatriation of the insured corpse to the home country specified in the employment contract, if the cause of death shall not be one of the exceptions stipulated in Chapter 3 herein.
- (2) Health benefits:
  - A. Expenses of medical examination, diagnosis, treatment and medicine as shown in the policy schedule.
  - B. Preventive measures, such as vaccinations including seasonal vaccinations and maternity and childcare, in accordance with the instructions issued by the Ministry of Health, as stipulated in Annex 1 attached to this Policy.
  - C. Expenses of hospitalization, including surgeries, same-day surgeries or treatment, pregnancy, and delivery.
  - D. Treatment of all Hereditary Diseases.
  - E. Disability cases within the limits specified in the Policy Schedule.
  - F. Medical interventions for long-term care that are life sustaining or affect outcomes with the exception of what have been exempted as stipulated in Chapter 3 herein.
  - G. Functional vision corrective intervention that prevent vision loss.
  - H. Medical equipment, and in order to describe the medical equipment systematically by a physician licensed from a certified center, the following must be complied with:
    1. The Insured shall have the relevant illness or condition, including heart diseases, hypertension, diabetes, and respiratory diseases.
    2. The medical equipment, licensed by the Saudi Food & Drug Authority, shall be provided through the preferred provider network accredited by the Insurance Company, according to the normal and reasonable prices, one time throughout the validity period of the policy, provided that the lifespan of the current equipment that it owns (if any) shall be expired.
    3. If the Insured requests a new medical equipment, there shall be a medical reason – during the effective period of the Policy – necessitating replacement of the current equipment. In addition, the Insurance Company may ask for the old equipment for replacement.
    4. The best medical practices shall be referred to and shall be linked to the principle of value-based health care when approving the insurance coverage. In addition, it shall be advised to consult the impact value study published by the international and local health technology assessment centers, if available.
  - I. Health benefits shall also include all the benefits stated in the schedule provided in Schedule (1) herein.

# Chapter Three

## Controls and Exclusions

**(A) This policy will not cover claims resulting from**

1. Complications from self-inflicted injury, excluding the costs of treating emergency cases (life-threatening injuries) as described by the Private Health Institutions Law and Regulations approved by the Ministry of Health, which determines how to dispatch emergency cases.
2. Complications from diseases resulting from the intentional abuse of some medications, stimulants, sedatives, substance abuse, etc., excluding the costs of treating emergency cases (life-threatening injuries) as described by the Private Health Institutions Law and Regulations approved by the Ministry of Health, which determines how to dispatch emergency cases.
3. Non re-constructive cosmetic surgeries.
4. General examinations, vaccines, drugs or preventive measures that do not require medical treatment or are not mentioned in this Policy (except for the preventive measures stipulated in the Policy or determined by the Ministry of Health, such as vaccinations as well as maternity and childcare).
5. Treatment received by the insured free of charge.
6. Recreational therapy, general physical health programs, and treatment in social welfare institutions.
7. Any illness or injury arising directly from the profession of the Insured.
8. All costs related to dental implants, dentures, crowns, bridges or cosmetic procedures including, but not limited to, teeth whitening, except for the benefits outlined herein.
9. Vision correction surgeries, excluding procedures that prevent vision loss.
10. The expenses of the transportation of the insured within and between cities in the Kingdom by means of transportation other than the licensed ground ambulance.
11. Hair loss, baldness or artificial hair.
12. Allergy tests of any nature, excluding those related to the medical cases that can Only be treated through these tests, or those related to prescribed medications, according to the medical proof and evidence.

13.  Equipment, treatments, drugs and hormone procedures, surgeries or treatment aimed at regulating reproduction, contraception, impotence, infertility, in-vitro fertilization, or any other method of artificial fertilization.
14. Any congenital weakness or deformity, unless it has a current or future life-threatening impact on the Insured.
15. Any additional costs or expenses incurred by the companion of the Insured during its stay at the hospital, except for hospital accommodation charges for one companion, as required by the best medical practices.
16. Treatment of acne.
17. Cases of human organ transplantation, according to the definition set out in the First Chapter of the Policy, excluding the additional benefits regarding organ transplantation. Knowing that artificial organs are managed as per the benefits and exceptions of the policy.
18. Joint replacement with exception to what have been listed as benefits or for the treatment of complications arising from a covered benefit such as joint replacement due to cancer or a trauma.
19. Personal risks set forth in Chapter 1 (Definitions) herein. Any sport other than what is mentioned in the definition chapter, must be submitted to the Council for decision. Alternative medicine procedures and medications. Artificial
20. and ancillary limbs.
21. Diseases that are classified by the Ministry of Health as pandemics or natural
22. disasters, and based on decision released by the Council. Eye glasses for persons over fourteen (14) years old.
23. Complications resulting from any previous illness or injury shall be excluded under
24. the provisions of this Policy.



25. Long-term care (Care for a long period) that are limited to nursing care or personal care with exception to the benefits listed in this policy.
26. Rehabilitation admissions for management of addiction and alcohol abuse

**(B) Except for the provisions of Section 2 herein, this policy shall not cover health benefits or corpse repatriation to home country in claims resulting from the following:**

1. War, invasion, acts of (foreign) aggression whether or not war is declared.
2. Ionizing radiations and pollution from radioactive activity of any nuclear fuel or waste resulting from the combustion of nuclear fuel.
3. Radioactive, toxic, explosive or other hazardous properties of any nuclear plant or any of its nuclear components.
4. The Insured service or participation in armed forces or police operations.
5. Riots, strike, terrorism, or its equivalents.
6. Accidents or chemical, biological, or bacteriological reaction, if those accidents or reactions are a result of occupational injury or occupational risk.

**(c) Hotels, dormitories, guest houses, resorts, convalescent centers, sanatoriums, places for the care of persons in custody, nursing home, or schools/institutes specialized in teaching deaf, autistic, etc. shall not be included under the concept of the Hospital described in this Policy.**

# Chapter Four

## General Conditions

## Policy Conditions

### (1) Proof of Validity:

This policy represents the basic level of insurance cover granted to the insured individual. This Policy shall not be valid unless confirmed by a schedule duly signed by an employee officially authorized by the Company. Likewise, any addition to this policy shall not be valid unless confirmed and accompanied with signed annex by an officially authorized assigned employee of the insurance company.

### (2) Effective Dates of Coverage:

- A. For Workers: Coverage shall become effective for the active employee as of the inception date shown in the Policy schedule, or from the date of employment contract for the workers joining work in a later time.
- B. For Dependents: Insurance cover shall become effective for dependents as of the date, during which the worker supporting them becomes insured or from the date they become dependents.
- C. For Fetus and Newborn infants:
  - 1. The insurance coverage for fetuses shall begin from the beginning of their inception until one month after birth, and its coverage shall be according to the limit of the Policy.
  - 2. Insurance coverage for newborn infants shall enter into effect immediately after delivery to a maximum of 30 days from the date of delivery, and its coverage shall be according to the limit of the mother policy.

### (3) Termination of the Insurance Coverage of the Insured Individuals:

- A. For Workers: Coverage of any worker under the Policy shall be automatically terminated in the following cases:
  - 1. If the Policy period ends or if it is canceled, as stipulated in the Policy Schedule.

2. Upon the exhaustion of the maximum limit of benefits stipulated in the Policy.
  3. If the Insured dies, without prejudice to paragraph (1) of Chapter 2 herein and as per the benefits limits in Policy Schedule.
  4. If the Insured leaves the Kingdom permanently.
  5. If the Insured transfers to a new employer.
- B. For Dependents: coverage under this Policy shall be automatically terminated in the following cases:
1. The dependent no longer qualifies as "dependent" as defined in Chapter 1 herein.
  2. If the Policy period ends as specified in the schedule.
  3. Upon the exhaustion of the maximum limit of benefits provided for in the Policy.
  4. If the Insured dies, without prejudice to paragraph (1) of Chapter 2 herein under the benefits limits stipulated in the Policy Schedule.
  5. If the Insured leaves the Kingdom permanently.
  6. If the Insured transfers to a new employer.
- (C) Payment of recoverable expenses of any current illness, which requires continued hospitalization, shall continue on the date of termination of coverage for the period necessary for treating such illness, provided that such period shall not exceeds 365 days as of the date of onset of said illness and within the limits of the maximum coverage amount stipulated in the Policy Schedule.

#### (4) Payment of Premiums (subscriptions):

- A. The Policyholder shall pay the health insurance premium due on each insured individual as agreed upon with the Company as of the effective date of the insurance coverage.
- B. If any portion of a premium is not paid, the Policy shall not be valid for a period longer than that covered by the portion paid, and the Company shall notify the Council accordingly.

#### (5) Cancellation:

The Policyholder may cancel this Policy at any time under a written notice sent to the Company within a minimum of 30 business days prior to the date required for cancellation, taking into account the rules governing forming

and managing insurance risk pools. In such case, the Policyholder and the Insurance Company shall comply with the following:

- A. The Insurance Company shall inform (under an official notice) the Council and the Preferred Provider Network once it receives a notice from the Policyholder – employer or the Insured – with regard to the Cancellation of the Policy.
- B. In the event of transferring the employment contract, the Employer shall execute another insurance policy with a qualified company, or the Employer shall include the insured individuals in a health coverage under another insurance coverage program approved by the Council. The new insurance coverage shall start as of the day following the cancellation of the previous policy.
- C. The employer may remove one or more employees from the Policy, after the Insurance Company receives proof that the Insured has left the Kingdom or transferred to a new employer.
- D. In the event of the cancellation of a Policy or removal/ deletion of an Insured, the Company shall ensure updating the data of the developed policy issuance system, according to the codes of cancellation or deletion.

In such case, the Company shall be liable to provide the Policyholder, within 60 business days from the cancellation date, with the remaining part of the premium for each insured individual whose claims did not exceed 75% of the annual premium. The refundable amount shall be calculated on proportional basis: (Refund = annual premium ÷ 365.25 days X the number of the remaining days)

- E. If the Policyholder refrains from paying the Company the expense exceeding the maximum limit of benefit within the period specified in Article (11) (Basis of Direct Debiting on the Company Account for the Service Provider Network) of the General Conditions of the Policy and due as a result of the arrangement for direct billing of the Company, the Company has the right to withhold refund of premiums, if any, and use such amounts to compensate for the expenses paid to the service

providers which should have been paid to the Company by the Policyholder.

- F. The Policyholder shall pay all expenses due to the Insurance Company within the specified period, and if such period expires, the Insurance Company has the right to refer to SIMAH as well as to the Insurance Company, in case the beneficiary is entitled to the benefit.

## Data:

### (6) Records and Reports:

The Policyholder must maintain a record for all of its employees and their insured dependents. This record shall include the individual's full name, sex, age, nationality, weight, height, classification and other basic information that might affect the management of this health insurance and the report on the premium rates. The insurance company shall be given access to such records to verify the accuracy of the information provided by the Policyholder, whenever needed. The Company shall, when requested, provide the Policyholder with any information about the Insured, in a manner consistent with the provisions of Personal Data Protection Law.

### (7) Adding and Deleting the Insureds and Related Contributions:

- A. The Policyholder shall immediately and officially notify the Company regarding all workers or dependents to be covered under the Health Insurance at the Policy effective date. The policyholder has the right to add an Insured on a proportional basis if there is a proof that the Employee joined the work for the employer, or requested deleting it in case it moved to work for another employer.
- B. For additions, to which what is mentioned in paragraph (A) here above does not apply, the addition of the numbers of new Insureds shall be effective as of the date of issuing the Policy, and its/their coverage shall be valid from the date of addition.

### (8) Eligibility:

- A. For Workers: Any person satisfying the definition of "Worker" shall be qualified for insurance in accordance with the Policy Schedule.
- B. For Dependents: Any person satisfying the definition of "Dependent" shall be eligible for insurance in accordance with the Policy Schedule.

### **Duplication of Insurance Coverage:**

#### **(9) Duplication of Insurance Coverage:**

If any person is identified as Dependent, in addition to being eligible for insurance as a worker, its health insurance as dependent will cease hereunder. When the husband and wife permanently reside together and have insurance as workers, the children in this case shall become eligible only as dependents of the husband, unless the employer wishes to add dependents - children - within the insurance coverage of the wife, provided that there shall be no Beneficiary who has two different insurance coverages during the same period.

#### (10) Non-Duplication of Benefits:

If there is a claim for recoverable expenses due under this Policy to the Insured, and these expenses are covered under another insurance, plan, program, etc., the Company shall then be responsible for paying such expenses and request the third parties to pay their proportional shares of such claim on behalf of the Insured.

### Financial Considerations

#### (11) Basis of the direct entry or in company's account at the Service Providers' Network:

- A. The service providers appointed by the Insurance Company shall send all medical expenses incurred hereunder, on a monthly basis and without prejudice to the days and periods specified in the document cycle in accordance with Article No. (90) of the Implementing Regulations. The Company shall evaluate and process such expenses, and notify the Policyholder when the expenses reach the maximum benefit limit, provided that the Company shall provide all information related to the remaining insurance limit for benefits and the Policy to the service provider before notifying that the expenses has reached the maximum benefit limit.
- B. If this limit is exceeded and the Company has already incurred it, it becomes entitled to claim for the refund of such expenses within a period not exceeding (60) business days from the date of informing the Policyholder of these expenses.
- C. If the Policyholder fails to comply with the reimbursement of such expenses to the Insurance Company within the specified period, it becomes entitled to refer to the Council to take the necessary action.
- D. The Insurance Company has the right to refer to SIMAH (SAMA) if the Policyholder fails to pay the expenses due to the Insurance Company



within the specified period, as well as to the Insurance Fund, if the beneficiary is entitled to the benefit.

## (12) Canceling a Service Provider from the Preferred Service Providers Network

- A. After issuing the Policy to the Employer, the Company is not entitled to delete or replace a health service provider from the Preferred Provider Network during the Insurance Period, except in the following cases:
1. If the health service provider has committed a fundamental breach of service provision, such as negligence or fraud.
  2. Upon termination of the Contract by the health service provider, provided that the Company shall provide a substitute for it at the same level in coordination with the Policyholder.
  3. Upon suspension/cancellation of its approval by the Council, provided that the Insurance Company shall provide a substitute for it at the same level in coordination with the Policyholder.

In all cases, the specified warning period and the cancellation conditions stipulated in the contract between the Insurance Company and the health service provider shall be observed. If a service provider is removed from the minimum network, it will continue to receive previously approved applicable policies until their expiry date. Insurance Company shall notify the Council when moving a service provider from an insurance category to another.

## (13) User charges (Copayment):

- A. Based on an agreement between the Policyholder and the Insurance Company, the deductible amount shall not exceed the amount specified herein. It shall be a binding and an obligatory condition for the Insured to pay the user charges amount (if any) as specified according to the contract concluded between the Policyholder and the Insurance Company. Any attempt by the Insured to refrain from the payment shall be considered a

violation of the Policy provisions and its terms and conditions. It shall become invalid for it until the payment of this amount.

- B. Cases of emergency and inpatient admission shall be excluded from Paragraph (A).
- C. The copayment amount charged to the Beneficiary shall not exceed what is specified in the Schedule of Health Benefits contained in Appendix No. (1).
- D. The amount of deductible or copayment for the outpatient clinics shall be separated from the service of dispensing medicines for one visit.
- E. The maximum deductible amount for medicines shall be calculated based on the price of the generic medicine or the brand Innovative medicine in the absence of a generic medicine registered with the Saudi Food & Drug Authority.
- F. The difference between the value of the generic medicine and the innovative medicine shall be paid in full by the Beneficiary if there is a registered generic medication alternative. The price difference shall not be included in the maximum deductible amount.
- G. Service provider must prescribe medical devices on the scientific name bases without specification of a trade name.
- H. An automatic substitution of the device name shall be done based on the beneficiary policy with accounting for the following exceptions:
  - a. if the healthcare provider requested no substitution with the following considerations:
    - i. To rely on a reasonable medical justification and attach documents justifying the application for approval by the Insurance Company, in case of obtaining the approval of the Company.
    - ii. If the Insurance Company deems that the medical justification is not possible, the beneficiary's shall pay the difference between the price of the two devices.

- b. If the beneficiary request dispensation of the medical devices as per the requested name, the beneficiary shall pay the difference between the price of the two devices.
- I. The amount of deductible must be clarified to the Beneficiary in details before providing the service based on the Policy.
- J. The Insured must be enabled to identify the costs of each health service provided to it upon its request.
- K. The Insured must be provided with the invoice for the health services provided.
- L. The Insured is entitled to obtain a proposal of the expected value of the costs and the copayment amount before starting the treatment.
- M. The deductible shall be calculated on the net value of the medical bill, with the exception of the price difference for innovative medicines.

#### (14) Reimbursement Basis:

- A. In cases of emergency, the Insured may obtain urgent medical treatment in centers other than the agreed upon with the Company on reimbursement basis. In such case, the Company shall, in accordance with the policy terms, conditions, limitations and exclusions, compensate the policyholder within a period not exceeding 15 business days for recoverable costs and expenses on the basis of prevailing prices, provided that it shall provide the Company with the supporting documents it requires within 30 business days as of the date of incurring such expenses.
- B. The Beneficiary has the right to upgrade his/her insurance category to a higher one in accordance with the provisions of the Contract of the Insurance Company with the employer or the dependent. In this case, the Beneficiary shall pay the difference between his/her insurance category and the higher insurance category, if approved.

### (15) Approvals:

In accordance with Article (90) of the Implementing Regulations, the parties to the insurance relationship, with respect to the obligation of each party individually, shall undertake the following:

- A. The service provider shall send a request for approval to cover the cost of treatment for the beneficiaries to the Insurance Company within a maximum of fifteen (15) minutes from the time of filling the application by the physician.
- B. The service provider shall, upon applying for approval for providing treatment to beneficiaries, ensure that the health services that will be provided to the Insured meet the criteria for the approval request.
- C. The service provider shall ascertain the limits of the subsidiary benefits provided to the Insured.
- D. The service provider shall ascertain that all basic data and information that support the approval request are submitted.
- E. The Insurance Company shall respond to the request submitted by the service provider for the approval of providing treatment to the Beneficiaries within a period not exceeding sixty minutes (60) from the time of submitting the request for approval. In case of disapproval, the reasons shall be formally clarified.
- F. The service provider shall respond to the Insurance Company's queries within 30 minutes of receipt of the query.
- G. All procedures related to the request for approving the provision of treatment between the Insurance Company and the service provider shall not exceed 60 minutes from the time of submitting the request.

### (16) Compensation for Expenses from a Traffic Accident:

- A. The Insurance Company that is notified of the traffic accident shall cover the Beneficiary's costs and follow up its medical treatment. The Insurance Company shall be liable for compensating the expenses of a medical claim resulting from a traffic accident, whether the Beneficiary is the perpetrator or the damaged, provided that the vehicle shall be licensed.

- B. The Insurance Company shall replace the Beneficiary (i.e. the injured person) in requesting third parties to pay their proportional share of that claim if such claim expenses are compensable for the injured person, meaning that they are covered under any plan, program, other insurance, etc.
- C. The Insurance Company is entitled to recourse against the Beneficiary if it waived the party causing the accident.

**(17) Expenses of Complications resulting from a Benefit Treatment:**

- A. The Insurance Company shall cover any costs for treating the complications arising from a benefit covered by the Policy according to the maximum limit specified herein, unless these complications are arising from negligence or medical error by the service provider, and a proof shall be given under a decision by the ministry of justice, establishing the responsibility of the parties of insurance relationship.
- B. The Insurance Company shall calculate the incidence of complications resulting from the treatment of the covered benefits, create an indicator based on the best common medical practices for follow-up, and inform the Council if the indicator is exceeded by one of the service providers.

**(18) Reasonable and Ordinary Medical Expenses:**

In contrast to the price lists agreed upon between the Insurance Company and the service provider for the services and medical expenses, the approved and customary medical expenses provided for the Beneficiary for emergency health services or outside the medical network are considered according to the level of the medical network assigned to the Insured.

**(19) Expenses of Corpse Repatriation to Home Country:**

The Insurance Company shall cover all costs of preparation and repatriation of the corpse of the Insured to the home country specified in the employment contract according to the maximum limit specified in the Policy.

## (20) Calculating the Amortization of the Benefit Limits

It shall be obligated to calculate the costs of the amortization of the benefit limits for the Insured by calculating the total cost on the Net basis, not the Gross bill.

## General Conditions:

### (21) Personal Hazards

The Council shall have the power to determine the hazard criteria for activities likely to involve personal hazards, and shall measure the extent to which it is subject to insurance coverage.

### (22) Verification of the insured's Health Condition:

- A. The Company has the right to and shall be given the opportunity, by an accredited medical entity, to examine the Insured requesting Recoverable Expenses at the expense of the Company for up to two times within sixty (60) business days following submission of the claim.
- B. The Policyholder or the Insured shall cooperate with the Company and allow all necessary measures that may reasonably be required by and paid for by the Company for the purpose of preserving any rights, claims, or legal compensations from third parties. The Policyholder may not assign such rights except with the Company's explicit or implicit consent.

### (23) Notices:

- A. All notices or other correspondence to the Company between all parties shall be formal.
- B. The Insurance Company shall notify the Policyholder with the Policy renewal or expiry date as follows:
  1. Sending a preliminary reminder notice to the Policyholder prior to the Policy expiration date of not less than 60 days.
  2. Sending a second reminder notice to the Policyholder prior to the Policy expiration date of not less than 30 days.

3. Sending a third reminder notice to the Policyholder prior to the Policy expiration date of not less than 15 days, and notifying the Council of it.
- C. The Insured (Policyholder) shall be obligated to notify the Insurance Company whenever any of its contact information, or of its subsidiaries, is changed.

**(24) Medical Declaration Form:**

- A. The Insurance Company shall adhere to the Unified Medical Declaration Form approved by the Council. The Policyholder shall submit such Form to the Insurance Company in case it is requested, provided that the Beneficiary shall fill it.
- B. Filling the Medical Declaration Form shall not require the insurance policies of the large and mega large enterprise (Except for beneficiaries added after issuing the Document).

**(25) Compliance with Policy Provisions:**

As a precondition to any liability of the company, the Policyholder and beneficiaries shall strictly comply with and execute all requirements, conditions, obligations and commitments stated in this Policy.

**(26) Construction:**

Unless the context otherwise required, or expressly stated the opposite:

- A. Any reference to a masculinity shall include femininity in its meaning.

**(27)** Any reference to this Document shall include in its meaning any amendments hereto or relating bylaws. **Penalties:**

Any disagreement or dispute arising out of or relating to the Policy shall be settled in accordance with Article (14) of the Cooperative Health Insurance Law.

**(28) Policy update:**

The council of health will be updating the policy every 3 years

# Chapter Five

## Insurance Drug formulary (IDF)



## Insurance Drug Formulary

- A.** The service provider shall prescribe medications, according to the generic name of the medicine, and shall observe the rules of the Saudi Food and Drug Authority regarding the exceptions.
- B.** The service provider shall prescribe medications, according to the medical indications associated with ICD-10, as approved in the basic benefits package.
- C.** A pharmacist shall automatically replace a brand name with the generic one if the drug is prescribed in a specific trademark, based on the Insured Policy, taking the following exceptions into account:
  - 1.** Irreplaceable generic drugs according to the regulations of the Saudi Food and Drug Authority.  
<https://www.sfda.gov.sa/sites/default/files/2021-08/SFDADDD.pdf>
  - 2.** If the Insured requested to be dispensed a drug with a specific trade name, the copayment amount shall be applied as specified in its policy. (0-50% of the selected trade name price)
  - 3.** If the treating physician requested not to replace the brand name for innovative drug, taking into consideration the necessity of the following:
    - i.** To rely on a reasonable medical justification and attach documents justifying the application for approval by the Insurance Company, in case of obtaining the approval of the Company, the copayment amount shall be applied only on the basis of the price of the approved generic as per its Policy.
    - ii.** If the Insurance Company deems that the medical justification is not possible, the copayment amount will be as 50% of the selected trade name price.
- D.** The medication cost shall be covered based on the scientific name according to the Insurance Council approved formulary( IDF)
- E.** The Approved IDF that is based on scientific name is binding for health care providers and insurance companies, and selection of the trade name to be covered is according to agreement between the Health care provider and insurance company.

- F.** Providers and insurance company shall comply with the IDF guidelines. In case the disease indication is not listed within the IDF, Evidence based clinical guidelines shall be considered (except for the diseases excluded from the coverage of the Policy).
- G.** The Insurance Company may, in coordination with the Policyholder, expand the drug services - i.e. providing the medication according to the brand name, coverage of acne treatment, reduction and cancellation of the deductible percentage according to the Policy agreement.
- H.** The service provider shall report any unavailability of drugs via the following e-mail to Saudi Food and Drug Authority: Shortage.Drug@sfda.gov.sa
- I.** The maximum deductible percentage for drugs shall be calculated according to the price of the generic (or the innovative if there is no generic alternative) based on agreement between the Health care provider and insurance company and product registered price in the Saudi Food and Drug Authority.
- J.** The service provider shall provide an alternative for the generic name within the same price range in case the suspension of drugs was not included in the suspended drugs in the local market by Saudi Food and Drug Authority.
- K.** The Insurance Company shall, in coordination with the service providers, work on updating the IDF and providing an alternative brand name in case of suspension, withdrawal or stopping any of the drugs included in IDF by Saudi Food and Drug Authority.
- L.** The service provider shall follow the regulations of Saudi Food and Drug Authority regarding dispensing and distributing pharmaceuticals <https://sfda.gov.sa/sites/default/files/2020-12/SFDA28122020aa1.pdf>.  
The service provider shall follow the procedures and controls of the Saudi Food and Drug Authority in terms of prescribing and dispensing narcotic drugs and psychotropic substances [https://old.sfda.gov.sa/ar/drug/drug\\_reg/DocLib/Drug12112019a1.pdf](https://old.sfda.gov.sa/ar/drug/drug_reg/DocLib/Drug12112019a1.pdf).
- M.** The service provider shall apply hazard reduction methods for approved and declared pharmaceuticals by the Saudi Food and Drug Authority: <https://www.sfda.gov.sa/ar/RMM> <https://sfda.gov.sa/en/RMM>.
- N.** The Insurance Company shall provide Pharmacy benefit management (PBM) to connect with service providers and undertake immediate adjudications of medication orders. In the absence of a PBM program, the IDF is set as the reference to providers.
- O.** Co-Insurance of medicines:
- i. Generic, non-prescription drugs and innovative treatment - with no generic alternative: 20% co-insurance, maximum participation in payment: SR 30

- ii. Innovative treatment - with a generic alternative: 0-50% coinsurance, maximum participation: Based on agreement between Employer and Insurance company

Copay	Medication Price(example)	Formula	Out of pocket Sharing
Generics	SAR 50	=20 % x Generics price	SAR 10
Replaceable Brand	SAR 200	=50% X price of Replaceable Brand	SAR 0-100

# Chapter Six

## Network

- A. Minimum Network:** It refers to the network of service providers that covers all Kingdom's regions and cities and its geographical scope, provided that it shall include all levels of health service.
- B. Preferred Providers Network (PPN):** A group of health service providers approved by the Council and identified by the Health Insurance Company to provide the service to the Insured. This is done directly by debiting the Insurance Company's account, provided that this network shall ensure the following levels of health services:
- Level One (Primary health care).
  - Level Two (Public Hospitals).
  - Level Three (Specialized or Reference Health Care).

Other complementary health services centers (such as: One-day surgery centers, pharmacies, Physical Therapy Centers, optical stores)

- C.** The Insurance Company shall provide the minimum network according to the Law of the Council of Health Insurance, taking into account that, when designing the minimum network, that government health facilities are include within the network for Saudi Beneficiaries for policies in accordance to article 11.
- D.** The Insurance Company shall provide the following specialized centers within the network: accident centers, heart and stroke centers, advanced centers for the treatment of tumors, advanced centers for the treatment of neurosurgery and chest, centers of critical care units for newborns and premature infants, in addition to the centers for high-risk pregnancy.
- E.** Diversity of Medical Network: The Policyholder may request the Insurance Company to expand the medical network for the minimum network approved

by the Council, provided that the expansion shall commensurate with the distribution of Beneficiaries

- F.** Quality of Medical Network: The Insurance Company shall provide the relevant specialties that mainly serve the Beneficiary in the design of the minimum network, provided that the Council shall, in the future, determine the specialties that must be available in the minimum network.
- G.** Telemedicine: The Insurance Company shall provide, within the minimum network, a Telemedicine service according to the classification of service providers approved by the Council to provide this service.
- H.** The Insurance Company may, in the event of non-approval to continue treatment in emergency cases, transfer the Insured, after the stabilization of health condition, to a service provider within the PPN of the Insured.
- I.** The Insurance Company may not, in the event of a transfer to another service provider, obligate the Insured to a specific service provider, as the Insured has the right to choose from its PPN.
- J.** The Insurance Company shall pay the claims directly to the non-contracted service provider for the period spent by the Insured to receive emergency treatment, based on the prices agreed upon with another health service provider of the same level and classification on the network.
- K.** The service provider shall provide health care services to those covered by any valid health insurance policies before the expiry or cancellation of the contract until the end of the insurance year as long as it is within the Preferred health care provider network for the Insured

- a. the Company bearing the responsibility to update the eligibility of the Beneficiary according to the start and end of the policies, which entails providing the service and claims accordingly.
- L. Following the issuance of the Policy to the Employer, the Insurance Company may not delete or replace a health service provider from the medical network specified for it during the validity period of the Policy unless:
- i. The Company observed a fundamental breach in the provision of the service from the health service provider, such as fraud or upon termination of the contract by the health service provider,
  - ii. or suspension/cancellation of its approval by the Council
- a. The company shall provide a substitute the deleted provider at the same level in coordination with the Policyholder, taking into account the specified warning period as well as the terms of cancellation stipulated in the contract concluded between them.
  - b. If a service provider was deleted from the minimum network, it shall continue to receive valid documents previously approved until its expiration date.
  - c. The Insurance Company shall notify the Council upon the replacement of a service provider from an insurance category to another.

- M.** The Company shall provide an adequate network of health service providers in terms of numbers and types of health care providers to ensure access to all health care services provided to beneficiaries without delay.
- N.** The insurance company is obligated to provide the Council of Health Insurance with an annual report on the minimum network, which includes a list of covered service providers, the speed of subscribers' access to services, the geographical availability of service providers to beneficiaries, the number of providers of categories of service providers for each subscriber
- O.** The Insurance Company shall provide a service provider network that meets the following access requirements, provided that it shall be determined based on the geographical scope and which shall be related to the national address of the Insured. The below conditions are indicative on determining the service provider network, and the Council shall later set the necessary condition:

  - 1.** For urban areas, a service provider network available to all Beneficiaries registered in the Policy within forty-eight (48) km or thirty (30) minutes from each person's place of residence or work, according to the availability of service providers approved by the Council in the region.



2. For areas other than urban areas (remote areas), the service provider network shall provide the services of primary health care doctors, hospital services and pharmacy within thirty (30) minutes or forty-eight (48) km from the place of residence or work of each registrant, according to the availability of service providers approved by the Council in the region. Provided that the services of other specialties shall be provided to all Beneficiaries registered in the policy within fifty (50 minutes) or eighty (80) km from the place of residence or work of each registrant, according to the availability of service providers approved by the Council in the region.

# Chapter Seven

## Table (1): Health Benefits Schedule

The purpose of the benefit	Benefit:	Appendix or related clinical guidelines
Empowering beneficiaries (Hospital Admission)	Insurance coverage for the costs of all hospital admission expenses, including surgery, or one-day treatment/surgery, pregnancy, and childbirth	According to the standard of common and customary medical practices
Beneficiaries Protection (Early and exploratory examination)	<p>The insurance coverage for periodic examinations is listed below according to the instructions issued by the Saudi Centre for Disease Prevention and Control listed in the National Manual of Periodic Examinations includes the following:</p> <ol style="list-style-type: none"> <li>1. Mammogram to detect breast cancer</li> <li>2. Pap smear to detect cervical cancer</li> <li>3. Fecal immunochemical test (FIT) or colonoscopy as per the medical necessity and best clinical practice to detect colon cancer.(Fecal immunochemical test) or colonoscopy according to medical need and best medical practices</li> <li>4. Behavioral or dietary consultations, or both, about healthy diet, and physical activity to prevent cardiovascular disease for adults with cardiovascular risk factors and have a Body Mass Index of more than 30 or those with two and more risk factors for heart disease</li> <li>5. Diabetes screening by fasting blood sugar test or checking (HbA1C) test</li> <li>6. Lipid profile test</li> <li>7. Bone densitometry (DEXA) to Detect Osteoporosis</li> </ol>	National Guideline for Periodic Health Examination issued by the Public Health Authority
Beneficiaries Protection (Vaccination)	Insurance coverage for preventive measures such as vaccinations, including seasonal vaccinations, maternal and childcare, under the instructions issued by the Ministry of Health and the Public Health Authority and specified in the policy in Annex No. (1) attached to this policy	Preventive measures approved by the Ministry of Health and the Public Health Authority
Beneficiaries Protection (Adult Vaccination)	Insurance coverage includes medical vaccines for adults in accordance with instructions issued by the Ministry of Health, including (Tdap), (PCV13), (PPSV23), and influenza vaccine.	National Vaccination Schedule (for Children) issued by the Ministry of Health
Beneficiaries Protection (Adult Vaccination)	Insurance coverage includes medical vaccines for adults in accordance with instructions issued by the Ministry of Health, including (Tdap), (PCV13), (PPSV23), and influenza vaccine.	National Vaccination Schedule for Adults
Health promotion and protection (Sexually Transmitted Diseases (STDs))	Insurance coverage for the treatment of sexually transmitted diseases (whatever the way the infection occurs) Include cover for Nongonococcal urethritis, Trichomoniasis, HIV, Syphilis, Human Papillomavirus (genetic warts), Neisseria gonorrhoeae, Genetic herpes, Chancroid	According to the standard of common and customary medical practices
Health Promotion (Women and Children's Health)	Insurance coverage includes follow-up of pregnancy and childbirth and following high-risk and low-risk medical pathways, according to approved clinical guidelines and based on eligibility criteria based on the best international clinical evidence and guidelines of high-risk pregnancy and in accordance with the requirements of the policy	Mother Health Passport (Low-Risk Pregnancy)

The purpose of the benefit	Benefit:	Supplements or clinical evidence
Promoting women's health (Family Planning)	Insurance coverage for temporary contraception that includes Hormonal contraceptives therapy and intrauterine devices according to the approved guideline	Contraception Clinical Practice Guidelines
Health Promotion (Women's Health)	Insurance coverage for comprehensive health care costs for menopausal and Perimenopause, including alternative hormone therapy	According to the standard of common and customary medical practices
Health Promotion (Newborn Health)	Insurance coverage of the first phase of the Newborn Screening for Hearing-Loss and Critical Congenital Heart Defects (CCHD) Program.	According to the standard of common and customary medical practices
Health Promotion (Newborn Health)	Insurance coverage of the costs of the National Newborn Screening Program to eliminate disabilities includes the examinations set out in Annex No. ([3]) attached to this policy.	Schedule of the National Newborn Screening Program to eliminate disabilities
Health Promotion (Child Health)	Insurance coverage of the costs of the immunization program (RSV) for children by the respiratory virus immunization schedule approved by the Ministry of Health.	Schedule of Respiratory Syncytial Virus (RSV) Immunizations issued by the Ministry of Health
Health Promotion (Child Health)	Insurance coverage of formula milk for newborns (in need) until the age of 24 months under the regulations governing the benefit of infant milk contained in Annex No. ([5]) and according to best medical practices	Controls governing coverage of baby milk Annex No. 5  and according to the approved manual for diagnosing milk allergy and malabsorption
Health Promotion (Child Health)	Cost of circumcision cases (male)	According to the standard of common and customary medical practices
Improving mental health	Insurance coverage of the costs of detecting the diagnosis and treatment of psychological cases.  For the following diseases: Depression, bipolar disorder, anxiety or stress, alcohol or drug use (not include hospitalization for rehabilitation), anger management, dealing with grief or loss, schizophrenia, post-traumatic stress disorder (PTSD) and eating disorders.	According to the standard of common and customary medical practices
Improving mental health	Insurance coverage of the costs of detecting diagnosis and treatment of autistic cases in accordance with the services provided to autistic patients contained in Annex No. ([4]) and with the benefit the limits set out in the policy table	Services provided to autistic patients
Improving mental health	Coverage of Alzheimer's cases treatment	According to the standard of common and customary medical practices

Empowering beneficiaries and reducing complications (Others)	Insurance coverage of the costs of treating Congenital Illness that may pose a current or future threat to life.	According to the standard of common and customary medical practices
Reducing disease complications (Other)	Insurance coverage of the costs of treating acquired valvular heart disease according to the benefit the limits specified in the policy schedule.	According to the standard of common and customary medical practices
Health promotion and protection (Dental)	All essential dental procedures and Root Canals and Emergencies	According to the standard of common and customary medical practices
Improving the ability and physical functions of beneficiaries (Rehabilitation)	Disability insurance coverage	According to the standard of common and customary medical practices
Improve ability and functionality For beneficiaries (Optical)	Optical insurance coverage for beneficiaries up to 14 years of age only	According to the standard of common and customary medical practices
Reducing complications chronic diseases — Improve the quality of life (Surgical Procedures)	<p>Insurance coverage for other procedures and surgeries in addition to sleeve gastrectomy surgery, if BMI exceeds 40 or 35 with complications, based on eligibility criteria based on the best evidence and international clinical guidelines and The Saudi Guide to Bariatric and Metabolic Surgery — according to the approved service package, the cost of covering surgery to treat obesity through one of the approved surgeries and bariatric surgery</p> <p>Laparoscopic Adjustable Gastric Banding (LABG), Laparoscopic Sleeve Gastrostomy, Roux-En -Y Gas Bypass, Mini Gastric Bypass/One anastomosis Gastric bypass, Biliopancreatic Bypass (Bypass) PD) — Duodenal Switch, Single anastomosis duodeno-ileal bypass (SADI) Biliopancreatic Division (BPD) Scopinaro</p>	<p>Approved Bundle</p> <p>The Saudi Guide to Bariatric and Metabolic Surgery</p>
Improving health (Surgical Procedures)	Insurance coverage of the costs of conducting an operation to collect organs from the donor in line with the benefit the limits set out in the policy schedule.	According to the standard of common and customary medical practices
Reducing complications of dialysis (Surgical Procedures)	Kidney transplant insurance coverage according to the services package approved by the CHI and in accordance with the benefit the limits set out in the policy schedule.	Approved Bundle

The purpose of the benefit	Benefit:	Supplements or clinical evidence
<p>Improve service quality and efficiency (chronic diseases)</p>	<p>Dialysis insurance coverage according to the package approved by the CHI</p>	<p>Approved Bundle</p>
<p>Facilitate access to the service For beneficiaries (home healthcare)</p>	<p>Provide home healthcare services for inpatients to enable them to complete their treatment at home according to best medical practices:</p> <ul style="list-style-type: none"> <li>• Wound care after surgery in medical case required</li> <li>• Provision of intravenous drugs after surgery and in medical cases required</li> <li>• Urinary catheterization care</li> </ul>	<p>According to the standard of common and customary medical practices</p>
<p>Facilitate access to the service For beneficiaries (Telemedicine)</p>	<p>The insurance coverage of telemedicine services provided by a center licensed by the Ministry of Health and in accordance with the rules and regulations approved by the CHI.</p>	<p>According to the standard of common and customary medical practices</p>
<p>Enhance the quality and efficiency of service (medical devices)</p>	<p>Medical hearing aids cost insurance coverage</p>	<p>According to the standard of common and customary medical practices</p>
<p>Enable beneficiary and facilitate access to services (medical devices)</p>	<p>Medical devices are covered based on what is prescribed by the approved clinical evidence and guidelines and the concept of value-based health care Including glucose monitors, insulin pump and blood pressure monitor according to approved guidelines</p>	<p>Saudi Clinical Guide for Diabetes</p>
<p>Enable beneficiary and facilitate access to services (Drug)</p>	<p>Approval of deductible for all Drug services and is separate from medical visits to outpatient clinics and applied according to the Insurance Drug formulary (IDF), with the adoption of generic drugs as an alternative to innovative drugs according to the policy schedule.  Medication Copayment must apply on October 2022, Mandatory Medication claim separation will be on 2023-based on the date specified by CHI later on according to the readiness assessment, earlier implementation can be applied based on agreement between both parties.</p>	<p>Insurance Drug Formulary (IDF)</p>
<p>Facilitate service access and enhance the quality of services (outpatient clinics)</p>	<p>Health care providers and Health insurance companies must implement the below process on 2023-based on the date specified by CHI later on according to the readiness assessment or at the earliest. <u>Deductible depending on the type of care provided:</u></p> <ol style="list-style-type: none"> <li>1. Visit primary care clinics (Family Medicine, GP, General Pediatrics, General International Medicine, General OB/GYN) regardless of the location of the clinic "Hospital or Health Center" <u>The primary care clinic shall be approved by the CHI: 0-5% with a maximum of 25 Saudi riyals</u> <ul style="list-style-type: none"> <li>• The services provided within primary care include preventive services, treatment for organic or psychiatric diseases for all ages and categories, non-critical maternity care and child health services.</li> <li>• Primary care service can be provided either in attendance or through telemedicine as required by the beneficiary's need. and referral must be accompanied with complete medical report.</li> </ul> </li> <li>2. Visiting specialized clinics after obtaining a referral from primary care clinics or ER: 0-10% with a maximum of 75 Saudi riyals</li> <li>3. Visit specialized clinics without obtaining a referral from primary care clinics: 0-50% with a maximum of 500 Saudi riyals, taking into account the following: <ul style="list-style-type: none"> <li>• The subsequent visit to specialized clinics resulting from a diagnosed medical need for specialized treatment according to medical needs and approved medical practices is treated as a referral visit and 10% participation rate applies to a maximum of 75 Saudi riyals.</li> </ul> </li> </ol>	<p>According to the standard of common and customary medical practices</p>
<p>Promoting health (Comprehensive Integrated Program for Diabetics Care)</p>	<p>A personalized health care plan created based on the patient's health profile to provide comprehensive health care services in accordance with medical best practices adopted by a medical team consisting of several health specialties, including, but not the limited to, a nutritionist, a podiatrist, a social worker, a health coach, and health educators. It also includes visits to eye specialists, kidneys, foot, heart, psychiatry and surgery in case of need, to ensure that diabetics receive the most advanced medical care, patient education and appropriate prevention and treatment of complications.</p>	<p>These services are provided through specialized clinics that provide comprehensive care to diabetics in the absence of integrated primary care services.</p>

# Chapter Nine

## Policy annexes

This chapter contains a set of appendices that are deemed as an integral part hereof, contain instructions and procedures related to the implementation of this policy. These appendices shall include the documents referred to in the articles hereof as follows:

1. [Preventive Procedures approved by the Ministry of Health Appendix # \(1\)](#)
2. [National Vaccination Schedule \(for Children\) issued by the Ministry of Health Appendix # \(2\)](#)
3. [Schedule of the National Newborn Screening Program to eliminate disabilities Appendix # \(3\)](#)
4. [Services Provided for Autism management Appendix # \(4\)](#)
5. [Controls governing coverage of baby milk Appendix # \(5\)](#)
6. [Schedule of Respiratory Syncytial Virus \(RSV\) Immunizations issued by the Ministry of Health Appendix # \(6\)](#)
7. [Providers Minimum Network Appendix # \(7\)](#)
8. [Declaration Form Appendix # \(8\)](#)
9. [Clinical guidelines and benefit Bundles Appendix # \(9\)](#)



### Appendix No. (1) Preventive Measures Approved by the Ministry of Health

1. Basic vaccinations for children include tuberculosis and HepB at birth, pentavalent vaccines (DTaP, HepB, Hib), 4 vaccines (DTaP, Hib), OPV, MMR and HepB are given according to the attached vaccination schedule in addition to any other vaccines may be introduced in the future according to the results of epidemiological analysis of diseases.
2. Comprehensive or specific national vaccination campaigns (PV, measles, MCV4 or any other vaccinations decided by the Ministry.
3. Nutritional surveillance and follow-up of children's development up to five years of age.
4. Treating some cases of infectious and endemic diseases as part of preventive measures taken.
5. Follow-up to expectant mothers and tetanus vaccination for pregnant women and women of childbearing age.
6. Insurance of births "delivery" in remote locations or where there are no hospitals.



### Appendix No. (3) Schedule of the National Newborn Screening Program to eliminate disabilities

The 17 diseases required to be detected in the early screening program for newborns

	Disease
1	(Congenital Hypothyroidism- CH)
2	(CAH-Hyperplasia Adrenal Congenital)
3	(Phenylketonuria - PKU)
4	(Maple syrup urine disease - MSUD)
5	(Propionic Acidemia - PPA)
6	(Methylmalonic Acidemia - MMA)
7	(Carboxylase CoA-Methylcrotonyl-3 Deficiency-3MCC)
8	(Efficiency Biotinidase)
9	(Glutaric Acidemia Type-1-GA)
10	(Isovaleric Acidemia)
11	(HMG-Co Lyase Efficiency - HMG)
12	(BKD- deficiency Ketothiolase-Beta)
13	(Arginosuccinase Acidemia- ASA)
14	(Citrullinemia)
15	(Medium-chain acyl-CoA dehydrogenase efficiency)
16	(Very long-chain AcylCoA dehydrogenase deficiency - VLCAD)
17	(GALT-Galactosemaia)

## Appendix (4) Services Provided to Autistic Patients

- Diagnosis of autism spectrum disorder.
- Medical diagnostic procedures (MRIs, gene tests and metabolic diseases)
- Psychological assessment and psychometric tests (IQ, CARS and GARS, ADOS, VINLAND).
- Medical rehabilitation (speech therapy, occupational therapy, behavior modification therapy).
- Early Intervention Program (for children under 6 years old with a minimum of 3 hours a day three times a week for 2 years).
- Medical and psychological consultations.

## E- Appendix (5) Infant Formula Dispensing Controls medically required indication for newborns until the age of 24 months

Based on the decision of the Cabinet No. (333) dated 9/8/1437 H, which includes the Saudi Health Council, in coordination with the Council of Health Insurance, to prepare regulated Controls Dispensing Infant Formula for newborns with medically required indication until the age of 24 months and covered by insurance.

Accordingly, regulatory controls have been prepared in coordination with the Council of Health insurance to cover the costs of insured Infant Formula for newborns with medically required indication until the age of 24 months if they are prescribed by a physician and cover the following cases:

1. Metabolic diseases.
2. National Newborn Screening Program Diseases
3. Milk or sugar allergy.
4. Malabsorption.
5. Preterm Baby, underdeveloped or severely underweight for gestational age, so it needs additional calories or growth enhancers for breast milk.
6. Metabolic diseases.

Dose Needed	Age at Middle of October	Babies Eligible for RSV Prophylaxis
Every 28 Prophylaxis Dose of RSV Starting Middle Days for 5 Months of October until Middle of March	<1 Year of age	Baby born < 29 weeks gestational age
	<1 Year of age	Preterm infants with BPD
	<2 Years of age	Children with pulmonary abnormality or Neuromuscular disease that impairs the ability to clear secretions from the upper airways and infants who are Severely immunocompromised
	<1 Year of age	Infants with certain hemodynamically significant heart diseases

**Appendix (6) Schedule of Respiratory Syncytial Virus Immunizations Approved by the Ministry of Health**

Date Of Next	Stamp	Name & Signature	Date	Doses
				First Dose
				Second Dose
				Third Dose
				Fourth Dose







## Appendix No. (9) Clinical guidelines and Benefit Packages

All approved clinical guidelines and evidence are periodically updated by the CHI Secretariat and accessible through the CHI's website

1. [Child Health Passport](#)
2. [Mother's Health Passport](#)
3. [National Guideline for Periodic Health Examination](#)
4. [Contraception Clinical Practice Guidelines](#)
5. [The Saudi Guide to Bariatric and Metabolic Surgery](#)
6. [Bariatric surgery bundle](#)
7. [Dialysis Bundle](#)
8. [Renal Transplant Bundle \(donor and recipient\)](#)
9. [Knee joint replacement bundle](#)
10. [Hip joint replacement bundle](#)
11. [Insulin Pump Policy](#)



# Chapter Ten

## Guidance Suggested Benefits

Gold and platinum benefit packages are suggested non-obligatory benefits to enable employer to add or add additional benefits in agreement with the insurance company.

وثيقة ضمان بلاتيني		وثيقة ضمان ذهبي	
مليون ونصف ريال سعودي		مليون ريال سعودي	
10,000 ريال سعودي	10,000 ريال سعودي	1,200 ريال سعودي	4,800 ريال سعودي
%0	%0	%0	%10
مبتكر مع وجود بديل جليس	جليس ومبتكر بدون وجود بديل جليس	مبتكر مع وجود بديل جليس	جليس ومبتكر بدون وجود بديل جليس
%15	%20	%25	%20
بالاتفاق ما بين صاحب العمل وشركة التأمين	30-0 ريال سعودي	بالاتفاق ما بين صاحب العمل وشركة التأمين	30-0 ريال سعودي
50,000 ريال سعودي +	50,000 ريال سعودي	50,000 ريال سعودي +	30,000 ريال سعودي
%0	%0	%0	%10
15,000 ريال سعودي	15,000 ريال سعودي	15,000 ريال سعودي	15,000 ريال سعودي
%20 - 0	%20 - 0	%20 - 0	%20 - 0
بحد أقصى 1000 ريال سعودي وتشمل علاج الليزاقولوتايد	بحد أقصى 1000 ريال سعودي وتشمل علاج الليزاقولوتايد	بحد أقصى 1000 ريال سعودي وتشمل علاج الليزاقولوتايد	بحد أقصى 1000 ريال سعودي وتشمل علاج الليزاقولوتايد
100,000 ريال سعودي	100,000 ريال سعودي	65,000 ريال سعودي	65,000 ريال سعودي
25,000 ريال سعودي	25,000 ريال سعودي	20,000 ريال سعودي	20,000 ريال سعودي
الحد الأقصى			
الحد الأدنى			
نسبة التحمل			
نسبة التحمل			
الحد الأعلى لنسبة التحمل الادوية			
حد خدمات الصحة النفسية			
نسبة التحمل			
حد علاج السنونة			
نسبة التحمل			
الحد الأقصى			
حد استبدال الركبة - الورك			
حد الوضع			
التشوهات الخلقية			
التعديلات الأخرى المقترحة			
الرعاية المنزلية			
الطب الاتصالي			
العيادات الخارجية			
المنافع الأخرى			

الحد الأقصى

الحد الأدنى

نسبة التحمل

نسبة التحمل

الحد الأعلى لنسبة التحمل الادوية

حد خدمات الصحة النفسية

نسبة التحمل

حد علاج السنونة

نسبة التحمل

الحد الأقصى

حد استبدال الركبة - الورك

حد الوضع

التشوهات الخلقية

التعديلات الأخرى المقترحة

الرعاية المنزلية

الطب الاتصالي

العيادات الخارجية

المنافع الأخرى

الحد الأقصى

الحد الأدنى

نسبة التحمل

نسبة التحمل

الحد الأعلى لنسبة التحمل الادوية

حد خدمات الصحة النفسية

نسبة التحمل

حد علاج السنونة

نسبة التحمل

الحد الأقصى

حد استبدال الركبة - الورك

حد الوضع

التشوهات الخلقية

التعديلات الأخرى المقترحة

الرعاية المنزلية

الطب الاتصالي

العيادات الخارجية

المنافع الأخرى

الحد الأقصى

الحد الأدنى

نسبة التحمل

نسبة التحمل

الحد الأعلى لنسبة التحمل الادوية

حد خدمات الصحة النفسية

نسبة التحمل

حد علاج السنونة

نسبة التحمل

الحد الأقصى

حد استبدال الركبة - الورك

حد الوضع

التشوهات الخلقية

التعديلات الأخرى المقترحة

الرعاية المنزلية

الطب الاتصالي

العيادات الخارجية

المنافع الأخرى

\* في حال تحطيت حد ال 500,000 ريال سعودي سيتم تغطية الفئات المستفيدة من قبل برنامج تغطية مستشفى الضمان الصحي (صندوق ضمان) للمؤسسات الصغيرة والمتوسطة.

## Bariatric Surgery Bundle/Guidelines

### The Clinical practice Guidelines for people who are going for Bariatric Surgery

Bariatric surgery remains the most efficacious weight loss intervention in individuals with obesity. Bariatric surgery should be considered as part of a comprehensive treatment delivered by a multidisciplinary team including GPs, physicians, surgeons, dietitians and psychologists. The potential benefits of surgery need to be assessed for each individual by suitably trained and experienced practitioners and balanced against the individual risk profile. Components of successful bariatric surgery care include an informed patient, tailored operation; committed multi-disciplinary team care and long-term follow up. All individuals considered for bariatric surgery need a careful risk to benefit assessment and optimization of health prior to surgery. Not all individuals in whom surgery is a potential treatment option will be suitable for surgery, especially if they have multiple and advanced complications.

#### Baseline assessment:

BMI	Class
<18.5	Underweight
18.5-24.9	Normal
25-29.9	Pre-obesity
30-34.9	Obesity class I
35-39.9	Obesity class II
≥40	Obesity class III
>50	Severe Obesity

#### Measuring Waist Circumference:

- ✓ Use a measuring tape that is checked monthly for stretching (replace if stretched).
  - Ask the person to remove heavy outer garments, loosen any belt and empty pockets.
  - Ask the person to stand with their feet close together (about 12–15 cm) with their weight equally distributed and to breathe normally.
  - Holding the measuring tape firmly, wrap it horizontally at a level midway between the lower rib margin and iliac crest (approximately in line with the umbilicus). The tape should be loose enough to allow the measure to place one finger between the tape and the person's body.
  - Record the measurement taken on an exhalation

### Initial process for Identification for suitability for Bariatric Surgery:

Their primary care physician or any other healthcare provider will initially identify patients. Candidates interested in weight loss surgery who fulfil the initial criteria will be referred to the bariatric information session.

Bioelectric Impedance analysis: method of measuring body fat directly. It shows linear relationship between body fat and all-cause mortality.

### Inclusion criteria for bariatric surgery:

Age: No age-based criteria is used as current longitudinal studies evaluating efficacy and safety endpoints do not apply specific age limits for the timing of surgery.

1. Clinically severe obesity (BMI > 40 kg/m<sup>2</sup>). It is the most effective treatment for morbid obesity, it leads to durable weight loss and improvement of co-morbidities
2. Metabolic Surgery should be considered as an option to treat T2D in patients with class I obesity (BMI 30.0–34.9 kg/m<sup>2</sup>) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin).
3. In adults with BMI > 35 kg/m<sup>2</sup> and severe co-morbidities Comorbidities associated with BMI 35-39.9 are:
  - T2D
  - Hypertension
  - Hyperlipidemia
  - Obstructive sleep apnea (OSA)
  - Obesity-hypoventilation syndrome (OHS)
  - Pickwickian syndrome (a combination of OSA and OHS)
  - Nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH)
  - Gastroesophageal reflux disease (GERD)
  - Venous stasis disease
  - Severe urinary incontinence
  - Debilitating arthritis

### Surgical Candidate:

The trigger point at which bariatric surgeons decide to surgery is BMI value, this point is 40kg /m<sup>2</sup>, and this is lower if a comorbid condition is identified and these are

1. Morbid obesity with BMI35kg/m<sup>2</sup>
2. History of repeated conservative treatment failures
3. No history of significant psychiatric disorders.

## Factors that will result in automatic refusal of weight loss surgery include:

- Active Alcohol or drug abuse.
- Lack of comprehension to risk, benefits and expected outcomes and lack of commitment to nutritional supplementation and long- term follow up required with surgery.
- Concurrent pregnancy or who expect to be pregnant within 12-18 months, surgery should be deferred.
- Medically correctable cause of Obesity
- Palliative cancer
- Contraindications to general anesthesia
- Correctable coagulopathy
- Uncontrolled Psychiatric illnesses
- Lack of comprehensive risk benefit ratio
- Severe heart failure or unstable coronary artery disease
- End-stage lung disease
- Active cancer diagnosis or treatment
- Cirrhosis with portal hypertension
- Severe impaired intellectual capacity
- Crohn's disease may be a relative contraindication to RYGB, BPD and SAGBP.
- Giant Ventral hernias
- Severe renal impairment and renal failure unless planned for renal transplant
- Chronic pancreatitis
- Severe intra-abdominal adhesions from previous open abdominal surgery.

## Assessment of patients for weight management program:

### Pre procedure evaluation of Bariatric surgery patients

Pre procedure evaluation must include a comprehensive medical history, psychosocial history, physical examination, and appropriate laboratory testing to assess surgical risk. The following checklist will help in determine the risk before surgery.

**History:** should look at the identification of Risk factors for obesity and identifying the complications of obesity.

#### 1. Screen for co-morbidities:

- a) Screen for diabetes according to standard of the American Diabetes Association
- b) Screen for hypertension according to Saudi hypertension guidelines
- c) Screen for hyperlipidemia according to US Preventive Task Force
- d) Evaluate for obstructive sleep apnea with a low threshold to refer patients to sleep medicine Specialist for evaluation
- e) Include in the history screening questions for the following and pursue as indicated:

- (i) Gastroesophageal reflux disease (GERD)
  - (ii) Cardiovascular disease: coronary, carotid, peripheral
  - (iii) Pulmonary disease, including asthma
  - (iv) Arthritis in weight-bearing joints
  - (v) Liver disease
  - (vi) Other physical limitations interfering with daily activity
2. Screen for emotional, cognitive, and motivational patient factors. The center or practitioner providing bariatric surgery must be accountable for a formal psychological evaluation of patients under consideration for bariatric surgery and an integrated, multidisciplinary pre and postoperative care program.
- a) Consider patient's motivation to engage in weight loss program with a validated tool
  - b) Screen for depression using a validated tool like PHQ9
  - c) Screen for dementia using a validated tool GPCOG score
3. Screen for additional exclusion criteria
- a) Female patients: screening for pregnancy, or intent to become pregnant within a year of surgery
  - b) Active life-limiting illness that would preclude benefit from weight loss
  - c) Screen for other factors as determined by the multidisciplinary care team

### Physical examination:

- Vitals Signs: Blood pressure/pulse/ temperature.
- Weight and BMI documentation
- Waist circumference
- Neck circumference
- Look out for secondary causes of Obesity (E.g. Cushing's disease)
- Polycystic Ovary syndrome
- Heart failure
- Stigmata of Chronic liver Disease, Abdominal Striae
- Umbilical incisional hernias
- Musculoskeletal Disease – osteoarthritis, Gout
- Skin Diseases
- Nutritional Diseases- Pallor of conjunctiva, atrophic glossitis, neuropathy
- Lower Limbs- lymphedema, Lipedema, venous insufficiency

### Routine Investigations:

#### Pre-Bariatric surgery panel:

**All patients must undergo an appropriate nutritional evaluation, including micronutrient measurements before any bariatric procedure and include:**

- CBC,
- Renal functions,
- Electrolytes,
- Lipid panel,
- Fasting blood sugar, Hba1c,
- Coagulation profile, INR, ABO type,
- Thyroid functions &TSH.
- Iron panel,
- Calcium,
- Albumin,
- PTH and Vitamin D
- Vitamin B1 may be considered in-patient undergoing RYGB, BPD, or OAGB

## Suspecting Sleep Apnea-

- Measurement of neck circumference (>17 inches in men, >16 inches in women)
  - Polysomnography for oxygen desaturation, apnea and hypo-apneic events
  - ENT examination for upper airway obstruction.
- **Suspected Cushing's syndrome** (moon face, thin skin that bruise easily, severe fatigue, striae)
  - Elevated late night salivary cortisol level (>7 nmol/l diagnostic, 3-7 nmol/l equivocal)
  - Repeatedly elevated measurements of cortisol secretion (late night salivary)
  - Cortisol or urine free cortisol, upper normal 110-138 nmol/l)
- **Suspected Polycystic Ovarian Syndrome:**
  - total testosterone, free and weakly testosterone, DHEAS,
  - Prolactin, TSH and early morning 17-hydroxyprogesteron
- **Cardiopulmonary evaluation** with (ECG, echocardiography, chest X-ray if cardiac disease or pulmonary disease suspected or high risk of cardiovascular disease.
- Patients with established cardiac disease, Hypertension, smoker and old age need cardiac assessment for the risk of general anesthesia
- **GI Evaluation:**
  - GERD needs assessment with H. pylori screening in areas of high prevalence;
  - Gallbladder Evaluation and upper endoscopy, if clinically indicated
- **Nutrient screening**
  - Iron studies, B12, and folic acid (RBC folate, homocysteine, methyl malonic acid optional), and 25-vitamin D (vitamins A and E optional); consider more extensive testing in patients undergoing malabsorptive procedures based on symptoms and risks.
  - Clinical nutrition evaluation by registered dietitian

## Medical Management and Coordination

1. Nutrition
2. Physical Activity
3. Behavior Therapy
4. Pharmacotherapy
5. Bariatric surgery

### **Begin comprehensive program of non-surgical care lifestyle modification according to ACC/AHA/TOS guideline or and other evidence-based guidelines**

1. Patient must meet emotional, cognitive, and motivational standards as judged by a mental health professional:
    - I. Pre-Surgical Clinical Psychology evaluation: Assess for individual psychological support/counseling. To assess the patient psychological readiness to bariatric surgery.
    - II. formal psychosocial-behavioral evaluation performed by a qualified behavioral health professional (i.e., licensed in a recognized behavioral health discipline, such as psychology, social work, psychiatry, or psychiatric nursing, and with specialized knowledge and training relevant to obesity, eating disorders, and/or bariatric procedures) to assess environmental, familial, and behavioral factors and risk for suicide should be required for all patients before a bariatric procedure.
  - III. Known Established Psychiatric Disease: Any patient with a known or suspected psychiatric illness, or substance abuse or dependence, should undergo a formal mental health evaluation before the procedure
2. Program includes the multidisciplinary care team as specified earlier in this document that includes the Obesity clinic team, surgical team, psychiatrist, Dietician and nutritionist and rehabilitation medicine.
  3. Program content should include:
    - a) Patient education on the benefit of weight loss
    - b) Instruction to maintain a healthy eating pattern that promotes metabolic health
    - c) Instruction and support in maintaining appropriate physical activity (at 180 minutes/week to promote health).
    - d) Behavioral therapy and management of behavioral disorders as needed
    - e) Management of Co-morbidities identified in the assessment as per the standard guidelines e.g.: diabetes with a target A1C between 7-9% depending on risk/benefit.
      - Pre-procedure glycemic control must be optimized using a diabetes comprehensive care plan, including healthy dietary patterns, medical nutrition therapy, physical activity, and, as needed, pharmacotherapy.
      - More liberal pre-procedure A1C targets of 7% to 8% (53 to 64 mmol/mol), are recommended in patients with advanced microvascular or macro vascular complications, extensive comorbid conditions, or long-standing diabetes in which the general goal has been difficult to attain despite intensive efforts.
      - Intra-/perioperative intravenous (IV) insulin is recommended for



- glycemic control in immediate postoperative patients with type 2 diabetes (T2D)
- The use of all insulin secretagogues (sulfonylureas and meglitinides), sodium-glucose cotransporter-2 inhibitors, and thiazolidinedione's should be discontinued and insulin doses adjusted (due to low calorie intake) to minimize the risk for hypoglycemia.
- Close monitoring of patient's anti diabetic medication is recommended. Decreasing doses and stopping medication to avoid hypoglycemia is important.
- Patient with T1DM can undergo bariatric surgery safely. We recommend co-management with endocrinology for these patients.
- Close monitoring of patient's anti diabetic medication is recommended. Decreasing doses and stopping medication to avoid hypoglycemia is important.
- In patients on thyroid hormone replacement or supplementation, thyroid-stimulating hormone (TSH) levels must be monitored after bariatric procedures and medication dosing adjusted, as dose reductions are more likely with weight loss.

### Management of Obesity – nonsurgical approaches

The goal of weight management is to improve health and to reduce the risk of obesity related co- morbidities

Devise Lifestyle modification program

1. The focus of lifestyle modification goals should be on improving health rather than reducing weight
2. Lifestyle modification should target –healthy eating patterns and physical activity and assisting in behavioral change.
3. Optimal dietary plan for achieving healthy body weight should be developed with a qualified and experienced health professional team together with the individual and family
4. When discussing management of obesity with the patient and family, health professionals are encouraged to create a nonjudgmental atmosphere and to address barriers to weight management

### Dietary Interventions:

The focus for dietary interventions should be healthier eating patterns without emphasis on caloric restriction in order to avoid metabolic adaptation and weight regain.

Target energy deficit of 500-100kilocalorie per day (3,500kcal/week).

Provide advice on dietary modification appropriate to the patient condition (type, quantity or frequency) to achieve appropriate and target weight loss.

Choose healthier foods like whole grains, cereals, fruits, vegetables and salads and reduce unhealthy choices like sugary drinks, animal fats.

Specific diets should not be prescribed to patients. Education on healthier eating pattern and better choices should be paramount. The focus of dietary interventions should be substantively weight losses rather than short-term temporary losses short-term energy restriction diets or prescriptions

Low-energy diets including caloric restricted diet can be used in certain circumstances with rapid improvement losses desired (e.g. mature women undergoing IVF treatments, weight loss prior to medical interventions)

### Physical Activity in adults:

1. Encourage individuals with pre-obesity and obese living with obesity to be physically active and to avoid sedentary behavior.
2. Aerobic physical activity (30–60 minutes of moderate to vigorous intensity most days of the week) can be considered for adults who want to:
  1. Achieve small amounts of body weight and fat loss. Achieve reductions in abdominal visceral fat and ectopic fat such as liver and heart fat even in the absence of weight loss; physical activity should target increasing cardiorespiratory fitness and mobility rather than weight loss
  2. Physical activity is paramount for weight maintenance after weight loss
  3. Physical activity is paramount in the maintenance of fat-free mass during weight loss;
3. For adults living with pre-obesity or obesity, resistance training may promote weight maintenance or modest increases in muscles mass or fat free mass and mobility.
  - a. Individuals can perform multiple small sessions of at least 10 minutes duration during the day to accumulate the required physical activity volume.
  - b. Clinically assess the individual physical fitness to perform the required physical exercise.
  - c. Build up the pace of physical activity gradually over time. The volume of physical exercise should be sustainable and tailored to the individual condition.
  - d. Sedentary individuals should start with 10-20 min of physical activity every other day during the first 2 weeks.
  - e. Vigorous intensity activity should be introduced gradually after an initial 4–12-week period of moderate intensity activity.

### Anti-obesity Pharmacotherapy Treatment

Anti-obesity pharmacotherapy may be prescribed in a manner consistent with their labeled indication. Medication options is liraglutide in addition to comprehensive lifestyle modification program.

Anti-obesity pharmacotherapy may be considered as an adjunct to lifestyle interventions in individuals with BMI >30 kg/ m<sup>2</sup> with or without comorbidities.

Patients should be assessed for medication success with weight loss of  $\geq 5\%$  of total body weight after 12 weeks of initiation of anti-obesity pharmacotherapy or 12 weeks after reaching maximal dose of pharmacotherapy when using medication that require gradual titration of doses. In the case of medication failure, the heterogeneity of the disease of obesity should be considered and another anti-obesity pharmacotherapeutic agent should be used.

Liraglutide Pharmacotherapy should be considered for treatment of weight regain after metabolic surgery (Type 2 surgical failure) or suboptimal weight loss after metabolic surgery (Type 1 surgical failure) defined as weight loss of < 50% of excess body weight (EBW) if no anatomical causes of failure can be identified.

### Assess patient response to intervention and patient safety

1. Director must document adherence to program requirements including:
  - a. All elements of program activities
  - b. Compliance with non-surgical activities – improved or stable medical markers (e.g.,
2. Weight, hypertension control, glycemic control)
  - a. If the patient has failed the program for comprehensive non-surgical treatment, the Director must document this finding in the medical record

### Fitness for surgery: appropriateness

1. Pre-procedure glycemic control must be optimized using a diabetes comprehensive care plan, including healthy dietary patterns, medical nutrition therapy, physical activity, and, as needed, pharmacotherapy.
2. More liberal pre-procedure A1C targets of 7% to 8% (53 to 64 mmol/mol), are recommended in patients with advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in which the general goal has been difficult to attain despite intensive efforts.
3. Adequate nutritional status to facilitate healing including review of need for vitamin supplements pre- and post-surgery
4. GI evaluation for Liver functions which helps in wound healing
5. pre-operative plan for management of opioid dependency if patient has taken opioids for more than three months
6. Avoidance of nicotine for at least four weeks pre-operatively
7. Screen for alcohol overuse, with management plan if screen is positive
8. Screen for depression with management plan if positive
9. Screen for dementia and address patient's ability to comply with therapeutic regimen

## Document optimal preparation for surgery:

Perform pre-operative history, physical, and screening lab tests based on review of systems:

1. Evaluate for pulmonary fitness
2. Obtain basic lab profile (please see above on required pre-operative labs).
3. Culture nasal passages to identify staphylococcal carrier state and treat accordingly
4. Screen for predictors of delirium
5. Obtain relevant consultations:
  - a. Evaluate for good dental hygiene in high-risk patients
  - b. Refer to anesthesia for pre-operative assessment including identification and Management of conditions such as sleep apnea and pulmonary hypertension
6. Request other consultations, as necessary
7. Review post-operative care plan, including long-term weight maintenance and nutritional plan.

### Bariatric Surgery Procedures

The following are endorsed by SASMBS 2019 guidelines

1. Laparoscopic Adjustable Gastric Banding (LABG)
2. Laparoscopic Sleeve Gastrectomy
3. Roux- En -Y Gastric Bypass
4. Mini Gastric Bypass/One anastomosis Gastric bypass.
5. Biliopancreatic Diversion (BPD) – Duodenal Switch
6. Single anastomosis duodenoileal bypass (SADI)
7. Biliopancreatic Diversion (BPD) Scopinaro.

### Revisional Bariatric Procedures

1. Removal of Gastric Banding
2. Conversion of Gastric Banding to R-Y Gastric Bypass, Sleeve, BPD, BPB-DS
3. Conversion of Vertical Banded Gastroplasty (VBG) to R-Y Bypass/sleeve/MGBP/BPD
4. Revision of gastric bypass or sleeve Gastrectomy to other procedures



Treatment	General	Potential acute complications	Potential chronic complications
Sleeve Gastrectomy	<p>Hospital stay 1-2 days Recovery 1-2 weeks Contraindications Poor surgical candidates Severe psychiatric disorder Intolerance to general anesthesia Pregnancy Drug or alcohol addiction Untreated or severe esophagitis Barrett's esophagus Severe gastroparesis Achalasia Previous gastrectomy Sometimes used as staged approach to gastric by-pass</p>	<p>Postoperative complications are rare Hemorrhage Anastomotic staple line leak Deep vein thrombosis Pulmonary emboli Dehydration Death</p>	<p>Disease relapse (Type 2 surgical failure also referred to as Weight regain) Marginal ulcer Dumping syndrome with reactive hypoglycemia Luminal stenosis Luminal twist and stricture (stomal narrowing) Fistula formation Iron deficiencies Protein malnutrition Other nutritional and mineral deficiencies (e.g. deficiencies of vitamins A, C, D, E, B and K, folate, zinc, magnesium, thiamine, etc.) Anemia (often related to mineral and nutrition deficiencies) Neuropathies (resulting from nutritional deficiencies) Gastroesophageal reflux disease Decreased bone density</p>
Gastric bypass	<p>Hospital stay 1-2 days Recovery 2 weeks Contraindications Poor surgical candidates Sever psychiatric disorder Intolerance to general anesthesia Pregnancy Drug or alcohol addiction Untreated esophagitis Unwillingness or an inability for appropriate long-term follow-up</p>	<p>Gastrointestinal obstruction Hemorrhage Anastomotic leaks Deep vein thrombosis Pulmonary emboli Dehydration Death</p>	<p>Disease relapse (Type 2 surgical failure also referred to as weight regain) Marginal ulcer Dumping syndrome with reactive hypoglycemia Small bowel obstruction caused by internal hernias or adhesions Anastomotic stenosis (stomal narrowing) Calcium decency Secondary hyperparathyroidism Iron decency Protein malnutrition Other nutritional and mineral deficiencies (e.g. deficiencies of vitamins A, C,D,E,B and K, folate, zinc, magnesium, thiamine, etc.) Anemia (often related to mineral and nutrition deficiencies) Metabolic acidosis Bacterial overgrowth Kidney stones Neuropathies (resulting from nutritional deficiencies) decreased bone mineral density Depression Potential need to re-operate</p>

## POST-OPERATIVE CARE AND RETURN TO FUNCTION

Standard process for post-operative care

1. Rapid recovery and mobilization of patients following surgery:
  - a. Provide accelerated physical therapy and mobilization if regional pain control is acceptable
  - b. Provide a patient-oriented visual cue to record progress on functional milestones required for discharge
  - c. Instruct patients in home exercise, use of walking aids, and precautions
  - d. Instruct "career" or family members to assist with home exercise regimen
  - e. If obstructive sleep apnea has been previously documented, encourage compliance with appropriate treatment
2. Ensure availability of physicians or appropriate medical consultants to assist with complex or

Unstable medical problems in the post-operative period.

3. Consider use of goal-directed hemodynamic interventions in moderate to high-risk patients.

All patients undergoing metabolic surgery have to be on nutritional supplementation after surgery indefinitely. These should be in a chewable form and should include a minimum of:

- 2 adult multivitamins plus minerals (each containing iron, folic acid, and thiamine)
- Calcium (1200-1500 mg elemental calcium). Calcium carbonate can be given safely for patients undergoing sleeve gastrectomy. For patients undergoing RYGB or OAGB Calcium citrate is recommended)
- Vitamin D (3000 IU) with target 25-OH vitamin D >30 ng/ml
- Iron 18-60 mg daily
- Vitamin B12
- Folic acid (if not part of the multivitamin preparation) and in women who are in childbearing age
- Micronutrient deficiency assessment should be done at 3 months, 6 months 12 months after bariatric procedures and then annually thereafter. Deficiencies should be treated when detected:
  - Ferritin
  - Folate
  - Calcium
  - Vitamin B12
  - Vitamin D
  - PTH
  - Iron
- HbA1c in patients who have diabetes or a history of diabetes.

- Annual screening for copper, zinc, and vitamin B1 deficiency should be considered in patients undergoing RYGB, BPD, or OAGB.

### Post-operative checklist

	Gastric bands	Sleeve gastrectomy	Roux-en Y gastric bypass	Biliopancreatic diversion with duodenal stich
Visits –initial	1 month	1 month	1 months	1 month
Interval stable	1-2 months	3 months	3 months	3 months
Once stable	6months	6 months	6 months	6 months
Blood tests	Yes	Yes	Yes	Yes
Liver function tests	Yes	Yes	Yes	Yes
CBC	Yes	Yes	Yes	Yes
Ferritin	Yes	Yes	Yes	Yes
Calcium	No	Yes	Yes	Yes
Vitamin D	No	Yes	Yes	Yes
Parathyroid hormone	Yes	Yes	Yes	Yes
Vitamin A initially and q6-12 months	No	No	Yes	Yes
Vitamin B12	Yes	Yes	Yes	Yes
Annually then q3-6 months if on supplementation	Yes	Yes	Yes	Yes
Zinc, copper	Possibly (1)	Yes (1)	Yes (1)	Yes (1)
Selenium	No (2)	No (2)	No (2)	No (2)
Lipid evaluation based on risk and therapy every 6-12 months	Yes	Yes	Yes	Yes
Bone density at 2 years	Yes	Yes	Yes	Yes

(1) Measure when concerns for example, if screening for iron deficiency anemia is negative, hair loss, pica, neutropenia.

(2) ) Measure when concerns for example, cardiomyopathy, chronic diarrhea

### Post-op Visits and Follow-up

Post bariatric surgery patients will follow-up with their Obesity Care team (surgeon, Obesity clinic) during the following intervals:

- 1week post-surgery
- 3 weeks post-surgery
- 3 months after post-surgery

- 6 months after surgery
- 1 year after the surgery
- Annual visits

Following comorbidities and general consideration should be dealt during the post bariatric surgery care irrespective of the procedure and during each visit this should be addressed

1. Avoid nonsteroidal anti-inflammatory drugs.
2. Adjust postoperative medications and medication reconciliation.
3. Consider gout and gallstone prophylaxis in appropriate patients.
4. Need for antihypertensive therapy with each visit.
5. Need for antidiabetic therapy with each visit.
6. Monitor progress with weight loss and evidence of complications each visit.
7. Monitor adherence with physical activity recommendations
8. Bariatric surgery patients require lifelong annual monitoring blood tests, including micronutrients. Encourage patients to attend for their annual blood tests.
9. Be aware of potential nutritional deficiencies that may occur and their signs and symptoms. In particular, patients are at risk from anemia and vitamin D deficiency, as well as protein malnutrition and other vitamin and micronutrient deficiencies. If a patient is deficient in one nutrient, then screen for other deficiencies too.
10. Symptoms of continuous vomiting, dysphagia, intestinal obstruction (gastric bypass) or severe abdominal pain
11. Require emergency admission under the local surgical team.

### **Bariatric surgery and pregnancy:**

1. Discuss contraception – ideally pregnancy should be avoided for at least 12-18 months post-surgery.
2. If a patient should plan or wish to become pregnant after bariatric surgery, alter their nutritional supplements to one suitable during pregnancy. Inform the obstetric team of the patient's history of bariatric surgery.



## HEALTHY EATING LONG TERM AFTER WEIGHT LOSS SURGERY

Healthy diet and lifestyle is key to long-term weight loss success.

The following should be followed up in the long-term for sustained weight loss

### 1. Eat 3 meals per day.

Missing meals can lead to you over eating later in the day. It can also increase the chances of snacking, grazing and making unhealthy food choices. Try to spread meals out evenly across the day to avoid the feeling of hunger or cravings. Missing meals can also lead to low levels of vitamins, minerals and proteins in your body. This can impact on how well your body functions and cause ill health. Use a side plate to help keep portion sizes small.

### 2. Make sure all meals are balanced

Include fruits or vegetables, proteins and starchy carbohydrates with each meal.

Protein rich foods include: meat, fish, eggs, beans, pulses and lentils, dairy and meat alternatives. These foods keep you full for a long time, help keep muscles strong and are important for growth and healing.

Starchy carbohydrates include: bread, rice, pasta, potatoes and cereals.

Choose whole grain/ brown options as able as these contain fiber which is important for bowel health and will keep you fuller for longer.

Fruits and vegetables can be fresh, tinned or frozen. You should include a wide range of different fruits and Vegetables in your diet as these contain vitamins and minerals. They are also a good source of fiber to help you feel fuller for longer.

### 3. Make sure you drink plenty of fluid

Aim for 2-3 liters of water a day. You can add no added sugar squash. Teas and coffees are also included but try to drink plenty of fluids that do not contain caffeine. Avoid fizzy drinks.

### 4. Stop drinking 30 minutes before a meal and start drinking 1 hour after.

### 5. Avoid Alcohol

## Standardized hospital Discharge process to be followed:

1. Arrange follow up with care team as per the protocol.
2. Evaluate social and resource barriers: evaluate and complete an assessment of the patient's home-going needs and potential barriers to care including support requirements. If a patient falls in the high or moderate readmission risk category and is eligible for home health, provide the patient with a list of home health agencies to choose from and complete a referral.
3. Reconcile medications
4. Provide patient and family/caregiver education with plan of care:
  - a. Signs or symptoms that warrant follow up with provider
  - b. Guidelines for emergency care and alternatives to emergency care
  - c. Contact information for bariatric surgeon and primary care provider
5. Ensure post-discharge phone call to patient by care team to check progress, with timing of call agreed with care team and primary care
6. Send post-discharge summary to primary care provider within two days of discharge

## References:

- 1 -Mechanick JI, Apovian C, Brethauer S, Garvey WT, Joffe AM, Kim J, Kushner RF, Lindquist R, Pessah-Pollack R, Seger J, Urman RD, Adams S, Cleek JB, Correa R, Figaro MK, Flanders K, Grams J, Hurley DL, Kothari S, Seger MV, Still CD. Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures - 2019 update: cosponsored by american association of clinical endocrinologists/american college of endocrinology, the obesity society, american society for metabolic & bariatric surgery, obesity medicine association, and american society of anesthesiologists - executive summary. *Endocr Pract.* 2019 Dec;25(12):1346-1359. doi: 10.4158/GL-2019-0406. Epub 2019 Nov 4. PMID: 31682518.
- 2- Wharton S, Kuk JL, Luszczynski M, Kamran E, Christensen RAG. Liraglutide 3.0 mg for the management of insufficient weight loss or excessive weight regain post-bariatric surgery. *Clin Obes.* 2019 Aug;9(4):e12323. doi: 10.1111/cob.12323. Epub 2019 Jun 10. Erratum in: *Clin Obes.* 2019 Dec;9(6):e12338. PMID: 31183988; PMCID: PMC6771702.
- 3- Wharton S, Kamran E, Muqeem M, Khan A, Christensen RAG. The effectiveness and safety of pharmaceuticals to manage excess weight post-bariatric surgery: a systematic literature review. *J Drug Assess.* 2019 Oct 17;8(1):184-191. doi: 10.1080/21556660.2019.1678478. PMID: 33110683; PMCID: PMC7567517.
- 4- Nor Hanipah Z, Nasr EC, Bucak E, Schauer PR, Aminian A, Brethauer SA, Cetin D. Efficacy of adjuvant weight loss medication after bariatric surgery. *Surg Obes Relat Dis.* 2018 Jan;14(1):93-98. doi: 10.1016/j.soard.2017.10.002. Epub 2017 Oct 9. PMID: 29287757.
- 5- Stanford FC, Alfaris N, Gomez G, Ricks ET, Shukla AP, Corey KE, Pratt JS, Pomp A, Rubino F, Aronne LJ. The utility of weight loss medications after bariatric surgery for weight regain or inadequate weight loss: A multi-center study. *Surg Obes Relat Dis.* 2017 Mar;13(3):491-500. doi: 10.1016/j.soard.2016.10.018. Epub 2016 Oct 27. PMID: 27986587; PMCID: PMC6114136.
- 6- Prevention and management of obesity: Saudi guideline update Al-Shehri Fahad S, Moqbel Mohammed M, Al-Khalidi Yahia M, Al-Shahrani Abdullah M, Abu-Melha Waleed S, Alqahtani Aayed R, Sabbahi Adnan A, Alkaud Alhasan M, Alfalah Haitham, Alqumaizi Khalid I, Saeedi Mohammad Y, Alharbi Mohammed Y, Elmourad Mourad, Mustafa Mustafa Salih, Alobaid Omar A, AlRajhi Saleh M, Alomary Shaker A, Al Eid Ahmed Jafar, Hussain Syed Arif, Alsa Yassin Hassan, Ibrahim Mohamed E, Alamri Fahad A, Almalki Muteb Z, Almoreished Talal FYear : 2016 | Volume: 4 | Issue Number: 1 | Page: 25-40
- 7- Scottish Intercollegiate Guidelines Network (SIGN). Management of obesity: A national clinical guideline. Edinburgh: SIGN; 2010. Available from url: <http://www.sign.ac.uk/pdf/sign115.pdf>.
- 8- The Scottish Government. Preventing Overweight and Obesity in Scotland: A Route Map towards Healthy Weight. Edinburgh: The Scottish Government, 2010. Available from <http://www.dumgal.gov.uk/CHttpHandler.ashx?id=10075&p=0>
- 9- David C.W. Lau, James D. Douketis, Katherine M. Morrison, Irene M. Hramiak, Arya M. Sharma, Ehud Ur, for members of the Obesity Canada Clinical Practice Guidelines Expert Panel. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children. *CMAJ* April 10, 2007 vol. 176 no. 8 doi: 10.1503/cmaj.061409
- 10- Australian Government: Department of Health and Aging. Clinical Practice Guidelines for the Management of overweight and obesity in adults, adolescents and children in Australia <http://www.healthyactive.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-adults.htm>. Canberra; 2003. Available from url: <https://www.healthyactive.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-index.htm>

## Renal dialysis Bundle

# Dialysis Care Bundles for Chronic Kidney Disease

### Introduction:

Dialysis care bundle is designed to be a structured method of improving care processes and outcomes in all End Stage Renal Disease patients with health insurance. It contains comprehensive renal dialysis care components and set of evidence-based practices. We have also included Home Hemodialysis management to ensure all option of renal replacement therapies are available for patients. The designed bundles is not meant to cover renal replacement therapy for Acute Kidney Injury.

### The following bundles are described below:

1. In center Hemodialysis
2. Home Hemodialysis
3. Peritoneal Dialysis

## The In center hemodialysis, session will bundle all of the following:

1. Dialysis unit meet all MOH requirements including manpower, structural requirements and Ultra-Pure water quality. The manpower will include:
  - a. Nursing 1:3 patients
  - b. Doctors:
    - One consultant: 120 patients
    - One Specialist: 80 patients
    - One Resident: 120 patients
    - One Dietician, Social worker and Pharmacist: 150 patients
  
2. The Bundle will include all of the following:
  - a. Vascular access for all patients with AV fistula is the priority unless it is clinical not feasible. All procedure related to the maintenance of vascular access and it related complications including catheter infection and malfunctions.
  - b. Meals during the treatment
  - c. Dialysis session 3 times per week for  $\geq 4$  hours, 3 times per week using high flux dialyzer
  - d. Visit by dietician, pharmacist and social worker at least 4 times per year.
  - e. Medications:
    - i. Intradialytic: Heparin, EPO and IV iron
    - ii. Calcium, One alpha, oral and IV Vit D, Vitamin D analogue, Renvela and Cinacalcet
    - iii. Multivitamin, Folic acid
    - iv. Blood pressure medications
    - v. Antibiotics related to catheter related infections.

f. Laboratory test:

Test	Admission	Monthly	3 months	6 months	Q 12 months
Creatinine	x	x			
Pre BUN	x	x			
Post BUN	x	x			
CBC	x	x			
Ferritin	x	x			
Tsat.	x	x			
Calcium	x	x			
Phosphorus	x	x			
Albumin	x	x			
iPTH	x		x	x	
Sodium	x	x			
Potassium	x	x			
Bicarbonate	x	x			
AST	x		x	x	
ALT	x	x			
Alkaline Pho.	x	x			
INR (For those on warfarin or going to procedure)	x	x			
HCV Ab	x			x	
HBsAg	x			x	
HBsAb	x			x	
IgM anti HBC	x				
HBcAb	x			x	
HIV combo	x				x
Fasting Blood Glucose	x			x	
25 OH Vit D	x			x	
Vit B12	x				x
Folic acid	x				x
MRSA screening	x			x	
Lipid profile	x			x	
Uric acid	x			x	
Blood group	x				
MRSA screening for patient with catheter	x				x

3. KPI: The below therapeutic target will be achieved in >70% of patients:
- a. Fistula > 70% of patients.
  - b.  $KT/V \geq 1.4$
  - c. Duration of dialysis treatment  $\geq 4$  hours
  - d. Calcium 8.4 – 10.0 mg/dl
  - e. Phosphorus 2.5-5.5 mg/dl
  - f.  $Ca \times Pho$  Index <55
  - g. IPTH 150-600 pg/ml
  - h. Hemoglobin 10-12 g/dl
  - i. Serum Ferritin 200 – 800 ng/ml
  - j. Transferrin Saturation 20-50%
  - k. Intradialytic weight gain  $\leq 4\%$
  - l. Seroconversion 0%
  - m. Serum Albumin  $\geq 3.5$  gm/dl
  - n. Patient satisfaction > 80% in the annual report
  - o. Pre-dialysis Blood pressure: SBP/DBP  $\leq 160/100$  mm H

## Home Hemodialysis Program Bundle

### Indications:

The services will be limited patients with mobility issue defined as bed bound or wheelchair bound.

### The dialysis session bundle will include the following:

1. All dialysis will be delivered by qualified dialysis nurses.
2. Patients can communicate with his physician through phone/video at any time during dialysis session.
3. Nurses has a full back up system for nursing or medical issues by the head nurse and nephrologist.
4. All patients' data will be connected to EMR system
5. Nephrology consultant/Specialist will be available for any emergency issue related to dialysis to visit the patient physically during the dialysis session.
6. Technical support for dialysis machine, water and IT system.
7. Blood samples will be collected during the dialysis session.
8. Dialysis session 3 times per week for 4 hours or more, 3 times per week using standard dialysis or Bag system utilizing 30-40 L per day for at least 4-6 days per week. For either system the providers will be accountable to provide all hardware related to the treatment which include dialysis
9. machine, portable RO, chiller.  
Provision of all dialysis and no dialysis supplies related to conducting to Home Hemodialysis session at Home such but no limited to disinfectant,
10. A minimum standard of ancillaries will be provided to include bag scales, bag warmer, bathroom scales, Blood Pressure (BP) machine, cleaning solutions, dressings, paper towels, dressing packs and glucometer.
11. Home visits by a consultant nephrologist and Dietician once per month and in case of emergencies related to dialysis treatment. In addition to a weekly visit by specialist.
12. Dialysis access management including insertion/Creation and maintenance. Similarly, handling all complications related to catheter/Graft/Fistula including infection and thrombosis.
13. Monthly water testing to ensure pure water quality based on AAMI criteria.
14. Dialysis unit back up agreement in case the dialysis could not be delivered at home. The reimbursement will be equivalent to in center dialysis.
15. Medications:
  - a. Intradialytic: Heparin, EPO and IV iron
  - b. Calcium, One alpha, oral or IV Vit D and Vitamin D analogue, Renvela and Cinacalcet
  - c. Multivitamin, Folic acid
  - d. Blood pressure medications
  - e. Antibiotics related to catheter related infections.



### 16. Laboratory testing as the following:

Test	Admission	Monthly	3 months	6 months	Q 12 months
Creatinine	x	x			
Pre BUN	x	x			
Post BUN	x	x			
CBC	x	x			
Ferritin	x	x			
Tsat.	x	x			
Calcium	x	x			
Phosphorus	x	x			
Albumin	x	x			
iPTH	x		x		
Sodium	x	x			
Potassium	x	x			
Bicarbonate	x	x			
AST	x		x		
ALT	x	x			
Alkaline Pho.	x	x			
INR (For those on warfarin or going to procedure)	x	x			
HCV Ab	x			x	
HBsAg	x			x	
HBsAb	x			x	
IgM anti HBc	x				
HBcAb	x			x	
HIV combo	x				x
Fasting Blood Glucose	x			x	
25 OH Vit D	x			x	
Vit B12	x				x
Folic acid	x				x
MRSA screening	x			x	
Lipid profile	x			x	
Uric acid	x			x	
Blood group	x				



**The patient KPI will be as the following:**

- a. Vascular access as a Fistula unless it is not clinically feasible.
- b.  $KT/V \geq 1.4$  for standard dialysis or  $Std Kt/V > 2.0$
- c. Duration of dialysis treatment  $\geq 4$  hours
- d. Calcium 8.42 – 10.0 mg/dl
- e. Phosphorus 2.5-5.5 mg/dl
- f. IPTH 150-600 pg/ml
- g. Hemoglobin 10-12 g/dl
- h. Serum Ferritin 200 – 800 ng/ml
- i. Transferrin Saturation 20-50%
- j. Intradialytic weight gain  $\leq 4\%$
- k. Seroconversion 0%
- l. Serum Albumin  $\geq 3.5$  gm/dl
- m. Patient satisfaction annual report of 80%
- n. Pre-dialysis Blood pressure: SBP/DBP  $\leq 160/100$  mm Hg

## Peritoneal Dialysis Bundle

1. Peritoneal Dialysis unit meet all MOH requirements.
2. Patient home visit before commencing peritoneal dialysis to ensure acceptable home set up to start PD therapy.
3. Availability of One PD nurse for every 25 patients and One Consultant for 120 patients.
4. Provision of all dialysis and no dialysis supplies related to conducting to peritoneal dialysis session at Home
  - a. A minimum standard of ancillaries will be provided to include bag scales, bag warmer, bathroom scales, Blood Pressure (BP) machine, cleaning solutions, dressings, paper towels, dressing packs.
  - b. Full range of standard dialysis fluids in all bag sizes, strengths including icodextrin to be delivered to the patient home.
5. Clinic visits minimum 4 times per year that include assessment by PD Nurse, Consultant Nephrologist, Dietician and Pharmacist.
6. Peritoneal dialysis catheter insertion and maintenance. Similarly, handling all complications related to PD catheter including peritonitis.
7. Peritoneal Equilibration Test (PET) to be done at 4-6 week of PD Initiation and then annually: The test may need to be done more frequent to adjust the PD prescription or three months after peritonitis.
8. Post PD peritonitis: once after every PD peritonitis.
9. Dialysis session 7 times per week using manual or cyler based on the patient preference.
10. Medications:
  - a. Calcium, One alpha, Vit D and Vitamin D analogue, Renvela and Cinacalcat
  - b. IV or Oral Iron and ESA.
  - c. Multivitamin, Folic acid, laxative.
  - d. All antibiotics for catheter or exit site related infections.
  - e. Blood pressure medications

### 11. Laboratory test:

Test	Admission	Q 3 months	12 months
Creatinine	X	X	
Pre BUN	X	X	
Post BUN	X	X	
CBC	X	X	
Ferritin	X	X	
Tsat.	X	X	
Calcium	X	X	
Phosphorus	X	X	
Albumin	X	X	
iPTH	X	X	
Sodium	X	X	
Potassium	X	X	
Bicarbonate	X	X	
AST	X	X	
ALT	X	X	
Alkaline Pho.	X	X	
HCV Ab	X		X
HBsAg	X		X
HBsAb	X		X
IgM anti HBc	X		X
HBcAb	X		X
HIV combo	X		
Fasting Blood Glucose	X	X	
HbA1C For diabetic patients only	X	X	
TSH	X		X
25 OH Vit D	X		X
Vit B12	X		X
Folic acid	X		X
MRSA screening	X		X
Lipid profile	X		X
Uric acid	X		X
Blood group	X		

12. Therapeutic Target Table for PD Patients to be checked every 3 months or more if needed to handle the patient's clinical condition.

No.	Therapeutic Parameter	Therapeutic Target	Achievable Percentage Among Patients
1	Creatinine Clearance (Ccr) / Week	50 L/week /1.73 m <sup>2</sup>	Minimum Ccr target is given as 60 L/wk in high and high-average transporters and 50 L/wk in low-average and low peritoneal transporters
2	A combined urinary and peritoneal Kt/Vurea per week	≥ 1.7	In all patients on chronic PD (CAPD and APD) once residual renal GFR is <4ml/min (renal Ccr <40L/week)
3	APD patients (on cycler) Minimum Ccr Minimum kt/v	45 L/wk / 1.73 m <sup>2</sup> 1.7	- Minimum Ccr in all patients - Minimum kt/v in all patients
4	Net ultrafiltration in anuric patients	0.75 L/day	In all anuric patients
5	Peritonitis rate / per patient-year	<1 episode / 24 months in adults	In all anuric patients A primary cure rate of ≥80% A culture negative rate of <20%
6	PD Exit site infection (ESI) rates	< 0.67 episodes/ patient/ year	
7	Calcium	8.4-10 mg/dl	≥70%
8	Phosphorus	2.5-5.5 mg/dl	≥70%
9	iPTH	150-600 pg/ml	≥70%
10	Hb	10-12 gm/dl	≥70%
11	Serum Ferritin	100- 700 ng/ml	≥70%
12	Transferrin Saturation	20-50%	≥70%
13	Serum Albumin	>=3.5 gm/dl	≥70%
15	Mean Arterial Pressure	≤105 mmHg	≥70%
18	Patient satisfaction/Quality of life	Treatment/Services	≥80%

References:

1. Standards guidelines for establishing, equipping and operating renal dialysis centers.
2. Saudi clinical guidelines for peritoneal dialysis.
3. <https://ispd.org/>
4. <https://kdigo.org/guidelines/>
5. <https://www.kidney.org/professionals/guidelines/hemodialysis2015>

## Living Donor Nephrectomy

### Perioperative Care of Living Donors

Day #	Details
Day -1	<ul style="list-style-type: none"> <li>- Admission</li> <li>- Type and screening</li> <li>- CBC</li> <li>- Coagulation profile</li> <li>- Renal profile</li> <li>- Urinalysis</li> <li>- CXR</li> <li>- ECG</li> </ul>
Day 0	<ul style="list-style-type: none"> <li>- Living donor nephrectomy (laparoscopic most of the time)</li> <li>- Surgical Prophylaxis</li> </ul>
Day 1	<ul style="list-style-type: none"> <li>- Blood work:               <ul style="list-style-type: none"> <li>▪ CBC</li> <li>▪ Renal profile</li> <li>▪ IVF</li> <li>▪ Encourage PO intake</li> <li>▪ Ambulation as tolerated</li> </ul> </li> <li>- Medications:               <ul style="list-style-type: none"> <li>▪ Analgesics</li> </ul> </li> </ul>
Day 2	<ul style="list-style-type: none"> <li>▪ Blood work:               <ul style="list-style-type: none"> <li>▪ CBC</li> <li>▪ Renal profile</li> <li>▪ LFT OD</li> <li>▪ Ambulation as tolerated</li> </ul> </li> <li>- Medications:               <ul style="list-style-type: none"> <li>▪ Analgesics</li> </ul> </li> </ul>
Day 3	<ul style="list-style-type: none"> <li>▪ Blood work:               <ul style="list-style-type: none"> <li>▪ CBC</li> <li>▪ Renal profile</li> </ul> </li> <li>- Medications:               <ul style="list-style-type: none"> <li>▪ Analgesics</li> </ul> </li> <li>- Discharge Home</li> </ul>

## Post-Transplant Living Donor follow up:

Domain	Details
Outpatient clinic visits by surgeon	<u>Frequency:</u> <ul style="list-style-type: none"> <li>- Once, 3 – 4 weeks post discharge</li> </ul>
Outpatient clinic visits by nephrologist or any practitioner	<u>Frequency:</u> <ul style="list-style-type: none"> <li>- Once, after 1 month</li> <li>- Once, after 6 months</li> <li>- Once, annually</li> </ul>
Laboratory	<u>Every visit:</u> <ul style="list-style-type: none"> <li>- CBC</li> <li>- Renal/ electrolytes panel</li> <li>- Fasting Glucose</li> <li>- Urinalysis</li> </ul>

## Kidney Transplantation

### Perioperative Care of Transplant Recipient

Day #	Details
Day -1	<u>Admission</u> <ul style="list-style-type: none"> <li>- Type and screening</li> <li>- CBC</li> <li>- Coagulation profile</li> <li>- Renal profile</li> <li>- CXR</li> <li>- ECG</li> <li>- Home medication</li> <li>- HD as indicated</li> </ul>
Day 0	<u>Kidney transplant surgery (recipient)</u> <u>Induction Therapy:</u> <ul style="list-style-type: none"> <li>- Anti-thymocyte globulin (ATG) target 4-6 mg/kg or Basiliximab</li> <li>- MethylPrednisolone 500 mg IV</li> </ul> <u>Maintenance Therapy</u> <ul style="list-style-type: none"> <li>- Tacrolimus (Prograf 0.05 mg/kg BID OR Advagarf 0.1 mg/kg OD)</li> <li>- Mycophenolate mofetil 1 gm po bid</li> </ul> <u>Blood work:</u> <ul style="list-style-type: none"> <li>- CBC Q 8h</li> <li>- Renal profile Q 8h</li> <li>- Nursing Ratio 1:1</li> <li>- IVF 1:1 Ratio</li> <li>- Urine output check every 1 h</li> </ul>

<p>Day 1</p>	<p><u>Induction Therapy:</u></p> <ul style="list-style-type: none"> <li>- ATG (2nd dose)</li> <li>- MethylPrednisolone 100 mg IV</li> </ul> <p><u>Maintenance Therapy</u></p> <ul style="list-style-type: none"> <li>- Tacrolimus (Prograf 0.05 mg/kg BID OR Advagarf 0.1 mg/kg OD)</li> <li>- Mycophenolate Moftile 1 gm po bid</li> </ul> <p><u>Renal transplant Doppler US</u></p> <p><u>Blood work:</u></p> <ul style="list-style-type: none"> <li>- CBC Q 8h</li> <li>- Renal profile Q 8h</li> <li>- Nursing Ratio 1:1</li> <li>- IVF 1:1 Ratio</li> <li>- Urine output check every 1 h</li> <li>- Encourage PO intake</li> <li>- Ambulation as tolerated</li> </ul>
<p>Day 2</p>	<p><u>Induction Therapy:</u></p> <ul style="list-style-type: none"> <li>- ATG (3rd dose)</li> <li>- MethylPrednisolone 80 mg IV</li> </ul> <p><u>Maintenance Therapy</u></p> <ul style="list-style-type: none"> <li>- Tacrolimus (adjust to trough level)</li> <li>- Mycophenolate Moftile 1 gm po bid</li> </ul> <p><u>Prophylaxis:</u></p> <ul style="list-style-type: none"> <li>- Valgancyclovir 450 mg od</li> <li>- Bactrim 1 SS daily</li> <li>- Nystatin mouth was 100000 IU/ml QID</li> </ul> <p><u>Blood work:</u></p> <ul style="list-style-type: none"> <li>- CBC Q 12h</li> <li>- Renal profile Q 12h</li> <li>- LFT OD</li> <li>- Nursing Ratio 1:2</li> <li>- IVF flat rate</li> <li>- Urine output check every 2 h</li> <li>- Encourage PO intake</li> <li>- Ambulation as tolerated</li> </ul>
<p>Day 3</p>	<p><u>Induction Therapy:</u></p> <ul style="list-style-type: none"> <li>- ATG (4th dose)</li> <li>- MethylPrednisolone 60 mg IV</li> </ul> <p><u>Maintenance Therapy</u></p> <ul style="list-style-type: none"> <li>- Tacrolimus (adjust to trough level)</li> <li>- Mycophenolate Moftile 1 gm po bid</li> </ul> <p><u>Prophylaxis:</u></p> <ul style="list-style-type: none"> <li>- Valgancyclovir 450 mg od</li> <li>- Bactrim 1 SS daily</li> <li>- Nystatin mouth was 100000 IU/ml QID</li> </ul>



	<p><u>Blood work:</u></p> <ul style="list-style-type: none"> <li>- CBC OD</li> <li>- Renal profile OD</li> <li>- LFT OD</li> <li>- Nursing Ratio 1:3</li> <li>- Decrease or stop IVF</li> <li>- Urine output check every 2 h</li> <li>- Ambulation as tolerated</li> <li>- Start medication teaching</li> </ul>
<p>Day 4</p>	<p><u>Induction Therapy:</u></p> <ul style="list-style-type: none"> <li>- Basiliximab (if used as induction therapy)</li> <li>- MethylPrednisolone 40 mg IV</li> </ul> <p><u>Maintenance Therapy</u></p> <ul style="list-style-type: none"> <li>- Tacrolimus (adjust to trough level)</li> <li>- Mycophenolate Mofetil 1 gm po bid</li> </ul> <p><u>Prophylaxis:</u></p> <ul style="list-style-type: none"> <li>- Valgancyclovir 450 mg od</li> <li>- Bactrim 1 SS daily</li> <li>- Nystatin mouth was 100000 IU/ml QID</li> </ul> <p><u>Blood work:</u></p> <ul style="list-style-type: none"> <li>- CBC OD</li> <li>- Renal profile OD</li> <li>- LFT OD</li> <li>- Nursing Ratio: Normal ratio</li> <li>- Stop IVF</li> <li>- Discontinue Foley Catheter</li> <li>- Ambulation as tolerated</li> <li>- Medication teaching</li> </ul>
<p>Day 5</p>	<p><u>Maintenance Therapy</u></p> <ul style="list-style-type: none"> <li>- Prednisolone 20 mg daily</li> <li>- Tacrolimus (adjust to trough level)</li> <li>- Mycophenolate Mofetil 1 gm po bid</li> </ul> <p><u>Prophylaxis:</u></p> <ul style="list-style-type: none"> <li>- Valgancyclovir 450 mg od</li> <li>- Bactrim 1 SS daily</li> <li>- Nystatin mouth was 100000 IU/ml QID</li> </ul> <p><u>Blood work:</u></p> <ul style="list-style-type: none"> <li>- CBC OD</li> <li>- Renal profile OD</li> <li>- LFT OD</li> <li>- Medication teaching</li> </ul> <p><u>Discharge Home</u></p>

### Post-Transplant recipient follow up:

Domain	Details
Outpatient clinic visits by surgeon	<p><u>Frequency:</u></p> <ul style="list-style-type: none"> <li>- Once, 3 – 4 weeks post discharge</li> </ul>
Outpatient clinic visits by nephrologist	<p><u>Frequency:</u></p> <ul style="list-style-type: none"> <li>- Twice weekly for the 1st month</li> <li>- Once weekly for the 2nd month</li> <li>- Every 2 weeks for the 3rd month</li> <li>- Monthly for the 4th to 6th month</li> <li>- Every 2 months for the 7th to 12th month</li> <li>- Every 3 to 6 months after the first year</li> </ul>
Laboratory	<p><u>Every visit:</u></p> <ul style="list-style-type: none"> <li>- CBC</li> <li>- Renal/ electrolytes panel</li> <li>- Calcium, magnesium, phosphorous, albumin</li> <li>- Fasting Glucose</li> <li>- Liver profile</li> <li>- Urinalysis</li> <li>- Drug level (Tacrolimus, Cyclosporin, others)</li> </ul> <p><u>Others with frequency:</u></p> <ul style="list-style-type: none"> <li>- Lipid profile – 3 months</li> <li>- Hb A1c – 3 months for the 1st year then annual for non-diabetics</li> <li>- PTH – 1st visit then month 3, 9, 12 and then yearly</li> <li>- Vit D – 1st visit then month 3, 9, 12 and then yearly</li> <li>- Albumin to creatinine ratio – 1st visit then month 1, 3, 9, 12 and then yearly</li> <li>- BK virus screening (PCR) – at month 1, 2, 3, 4, 5, 6, 9, 12 and then yearly</li> <li>- Cytomegalovirus screening (CMV) PCR at month 1, 2, 3, 4, 5, 6, 9, 12 and then yearly</li> <li>- HBV and HCV screening – yearly</li> </ul>
Others	<ul style="list-style-type: none"> <li>- Osteoporosis screening (DEXA scan) – every 2 years</li> <li>- Malignancy screening – as per guidelines for general population</li> <li>- Vaccination – as per guidelines for general population</li> </ul>

### Medications used:

Family	Examples
Immunosuppression medications	<p><u>Induction:</u></p> <ul style="list-style-type: none"> <li>- Anti-thymocyte globulin</li> <li>- Basiliximab</li> <li>- MethylPrednisolone</li> </ul> <p><u>Maintenance</u></p> <ul style="list-style-type: none"> <li>- Prednisolone</li> <li>- Calcineurin inhibitors: Tacrolimus or Cyclosporine</li> <li>- Antimetabolites: Mycophenolate Mofetil or Mycophenolate sodium, Azathioprine</li> <li>- mTOR inhibitors: Sirolimus or Evirolimus</li> </ul>
Prophylactic medications*	<ul style="list-style-type: none"> <li>- Nystatin mouth wash – for 1 month</li> <li>- Valgancyclovir – for 3 months</li> <li>- Trimethoprim/Sulfamethoxazole SS for 6 months</li> <li>- Isonazide + Vit B6 for 9 months, for patient with Latent TB</li> <li>- Entacavir for patient with Hepatitis B virus</li> </ul>
Acute rejection*^	<ul style="list-style-type: none"> <li>- Anti-thymocyte globulin</li> <li>- MethylPrednisolone</li> <li>- Intravenous immunoglobulin (IVIG)</li> <li>- Rituximab</li> <li>- Plasmapheresis</li> </ul>
Desensitization protocol*&	<ul style="list-style-type: none"> <li>- Intravenous immunoglobulin (IVIG)</li> <li>- Plasmapheresis</li> <li>- Rituximab</li> </ul>

\* These medications are to be used as per the guidelines

^ Acute rejection needs to be confirmed by a percutaneous kidney graft biopsy and managed with one or combination of these medications as per the guidelines

& In the presence of immunological barriers (ABO incompatibility or donor specific antibodies) transplant center may start Desensitization protocol using these interventions as per the guidelines

## Knee joint replacement approved bundle

### Knee Replacement surgery Bundle

#### Preoperative investigation:

1. Radiographs for surgical planning:
  - a) AP, Weight Bearing
  - b) Lateral, in 30 degrees of Flexion
  - c) Skyline view
  - d) Full Length Hip to Ankle (if analog 51" Cassette)
  - e) CXR
2. Blood tests: CBC, Kidney profile, PT/ INR, Hgb A1C , Lipid Profile, fasting blood sugar (optional ). LFT, (Optional & Surrogate for Hepatitis marker)
3. ECG

#### Anesthesia clearance:

1. Medical clearance if demanded by anesthesia:
  - a. Internal medicine, cardiology, nephrology etc.

#### Admission:

- Preadmission – (the day before surgery) or same day admission

#### Pre op medications:

1. AB Prophylaxis: Upon Induction no more than 60 minutes from incision, Duration, 24 hours from anesthesia end time, IV.
2. Tranexamic Acid use is optional to minimize risk of bleeding and blood transfusion (dose and route based on institution protocol)
3. Blood transfusion as deemed necessary ( at any stage , can be pre op , intra op or post op)

### Post op medications:

1. Oral, IM and IV pain meds
2. Regional anesthesia modalities such as Adductor canal block
3. Post op antibiotics for 24 hrs.
4. Post op anti-coagulations:
  - a. ACCP guidelines recommend the use of: LMWH, low-dose UFH, VKA, fondaparinux, apixaban, dabigatran, rivaroxaban (all Grade 1B) or IPCD (Grade 1C) for at least 10 to 14 days and up to 35 days

### Postoperative inpatient rehabilitation:

1. A physiotherapist should offer rehabilitation, commencing on the same day of surgery if feasible and should not be delayed more than the first day postoperatively to patients with primary elective knee replacement. Inpatient rehabilitation settings should be focused on activity-based interventions (**Henderson et al 2018**). Rehabilitation should include\*:
  - a. Patient education on preventing any potential postoperative complications/side effects and managing activities of daily living
  - b. Mobility training with proper selection of assistive devices
  - c. strengthening and range of motion exercises
  - d. Early and safe mobilization
  - e. Physiotherapist should give education on self-directed and home exercise before the patient leaves the hospital
2. Occupational therapist will offer rehabilitation as needed starting from the second postoperatively , the services will include:
  - a. Training and recommending new techniques for self-care including bathing, toileting, dressing, carrying out daily activities in the safest and most energy conserving way possible.
  - b. Prescribing the proper self-care tools equipment to prevent complications and falls at home.

Expected LOS: 3-6 days

### Discharge Criteria:

1. BUN, Creatinine, lytes, should be NORMAL
2. HGB not Less than 8 g/dl
3. Stable vital signs
4. Able to go up & down 3 steps (physiotherapy clearance)
5. Patient can ambulate for 50m using walker

### Recommended outpatient clinic follow-up:

1. 2 weeks post-surgery
2. 6 weeks post-surgery
3. 12 weeks post-surgery
4. 1-year post-surgery

### Postoperative outpatient rehabilitation

For patients with primary elective knee replacement:

1. Patient will be offer supervised outpatient rehabilitation for physical therapy and occupational therapy to patients who:\*
  - a. have difficulties managing activities of daily living **or**
  - b. have ongoing functional impairment/limitations leading to specific rehabilitation needs **or**
  - c. Find that self-directed rehabilitation is not meeting their rehabilitation goals.
2. Home exercise program or outpatient exercise program may include one or combination of the following: knee ROM exercises, strengthening exercise for lower extremities muscles (open and closed chain exercises), stretching exercises, functional exercise, gait training, balance training exercises, upper extremity exercises, endurance training (little evidence on short-term improvement in physical function - **Artz et al 2015**)

**\* NICE (Oct 2019): Guideline - Joint replacement (primary): hip, knee and shoulder**

Postoperative rehabilitation may be divided into phases (**Maxey & Magnusson: Rehabilitation for the postsurgical orthopedic patient. 3<sup>rd</sup> ed, 2013. St. Louis: Elsevier**)

#### Phase I (Inpatient acute care 1-5 days):

1. Patient education to control postoperative swelling (cryotherapy , elevation and circulatory ankle exercises) and positioning to prevent knee flexion contracture
2. Breathing exercises
3. Inspect wound for drainage, erythema, and excessive pain
4. Active-assisted and/or AROM knee/hip extension and flexion.
5. CPM setup (in case patient is unable to perform active ROM) and patient instruction beginning with 0°-40° and progressing 5°-10° as tolerated 5-10 hrs./day
6. Isometrics—quadriceps, hamstrings, and gluteal sets: 10 repetitions three times
7. Transfer and bed mobility training.
8. Gait training with weight bearing as tolerated or as indicated (using proper walking aid) in knee immobilizer until adequate quadriceps control is restored.
9. After second day, progress with all exercises (repetitions, resistance and knee ROM) , gait training (distance/type of aid us

### Phase II (Outpatient care 6-14 days)

1. Continuation and progression of interventions from phase I
2. Transfer training (car, sit-stand with varying seat heights)
3. Progressive gait training using appropriate assistive device
4. Aggressive knee extension and flexion exercises
5. A/AROM—flexion (seated, on step, on bicycle)
6. AROM—SLR, heel raises, leg curls, step-ups, step-downs, one-fourth squats
7. Joint mobilization
8. Soft tissue and myofascial release (respecting incision)
9. Careful ongoing monitoring of edema

### Phase III (Outpatient care 3-12 weeks)

1. Initiate aquatic therapy if available with concurrent land-based treatment
2. Continuation of ROM stretches and soft tissue procedures.
3. Progression of (repetitions and/or intensity of resistance) with previous exercises
4. Squats, leg press, and bridging and other functional exercises as needed.
5. Bicycling, walking, or swimming for cardiovascular conditioning 20 minutes three to five times a week (as indicated per general health issues)
6. Hip strengthening/stretching exercises.
7. Return to pre-morbid level of daily activities

### Essential Implants and equipment's:

- SFDA approved Primary total knee replacement components including (femur and a tibial implants with a tibial insert)
- Walker

## Hip Replacement Surgery Bundle

### Preoperative investigation:

1. Radiographs for surgical planning:
  - a) AP, Weight Bearing pelvic x-ray
  - b) AP and Lateral x-ray of the affected hip
2. CXR
3. Blood tests: CBC, Kidney profile, PT/ INR, Hgb A1C , Lipid Profile, fasting blood sugar (optional ). LFT, (Optional & Surrogate for Hepatitis marker), cross and match of 2 units of PRBCs
4. ECG

### Anesthesia clearance:

- Medical clearance if demanded by anesthesia: Internal medicine, cardiology, nephrology etc.

### Admission:

- Preadmission – (the day before surgery) or same day admission

### Pre op medications:

1. AB Prophylaxis: Upon Induction no more than 60 minutes from incision, Duration, 24 hours from anesthesia end time, IV.
2. Tranexamic Acid use is optional to minimize risk of bleeding and blood transfusion (dose and route based on institution protocol)
3. Blood transfusion as deemed necessary ( at any stage , can be pre op , intra op or post op)

### Post op medications:

1. Oral, IM and IV pain meds
2. Regional anesthesia modalities
3. Post op antibiotics for 24 hrs.
4. 2 units of PRBCs
5. Post op anti-coagulations: ACCP guidelines recommend the use of: LMWH, low-dose UFH, VKA, fondaparinux, apixaban, dabigatran, rivaroxaban (all Grade 1B) or IPCD (Grade 1C) for at least 10 to 14 days and up to 35 days



## Postoperative inpatient rehabilitation:

### Phase I: In-Patient Post-operative Phase (Day 1 – 6):

A physiotherapist should offer rehabilitation, commencing on the same day of surgery if feasible and should not be delayed more than the first day postoperatively.

#### Goals:

1. Knowledge & adherence to THR precautions.
2. Safe independent transfer in and out of bed, chair & toilet seat.
3. Ambulate independently using walking aid on level/stairs.
4. Control edema.
5. Independent with basic activities of daily living
6. Independent in-home exercise program

#### Physical Therapy treatment strategies

1. Cryotherapy to manage pain and control swelling
2. Strengthening exercises
3. Gait training with the use of assistive devices
4. Avoid reciprocal steps on the stairs
5. Range of motion exercise

#### Occupational Therapy treatment strategies

- Training and recommending new techniques for self-care including bathing, toileting, dressing, carrying out daily activities in the safest and most energy conserving way possible.
- Prescribing the proper self-care tools equipment to prevent complications and falls at home.

#### Precautions:

- Weight bearing per physician order
- No hip flexion beyond 90 degrees
- Avoid leg crossing
- Avoid hip abduction and internal rotation in supine and side lying positions (a pillow can be placed, or wedge can be placed to maintain correct position)
- Avoid lying on the operated side
- Avoid pillows under knee to avoid contracture
- No prone lying
- No bridging
- Avoid sitting on low, soft surfaces and to use a raised toilet seat for 6 weeks – 3 months

Expected LOS: 3-6 days

#### Discharge Criteria:

1. BUN, Creatinine, lytes, should be NORMAL
2. HGB not Less than 8 g/dl
3. Stable vital signs

4. Able to go up & down 3 steps and walk for 50 m with an assistive device (Walker)
5. Patient and caregiver demonstrate understanding of all post-operative precautions and home exercise program

### Recommended outpatient clinic follow-up:

1. 2 weeks post-surgery
2. 6 weeks post-surgery
3. 12 weeks post-surgery
4. 1-year post-surgery

### Postoperative outpatient rehabilitation

Phase II: Out-patient Phase [Early flex/strengthening] (Day 7 to week 8)

#### Goals:

- Manage Pain & swelling
- Achieve independent gait with or without assistive device
- Achieve functional Hip range of motion within the precautions/dislocation parameters
- To be independent in activities of daily living

#### Treatment

- Progress hip strength
- Closed chain strengthening exercises
- Progress forward step-up (10-20cm)
- Static and dynamic balance and proprioceptive activities as appropriate
- Gait training
- Stationary bike
- Cryotherapy
- Pool therapy

#### Precautions

- Avoid heat therapy
- Avoid prolonged sitting
- Avoid pain during exercise and activities
- Avoid reciprocal stairs training until functional hip range of motion is achieved

#### Criteria for Advancement

- Controlled Pain & swelling
- Hip hypertext 0-150
- Safe gait with an assistive device
- Ascend 20 cm step
- Achieve independence in self-care and activities of daily living
- Absence to minimal Trendelenburg and/or antalgic gait pattern.
- Adequate hip abductor 3+/5

#### Outcome measures

- Determine baseline in Range of motion and Muscle strength
- Time up and go
- 6 minute walk test

### Phase III: Advanced strengthening & return to function: (Week 9-14)

#### Goals:

- Progress full functional ROM within hip precautions
- Improve gait and stair use without assistive device
- complete resolution of edema
- Advance strengthening including functional closed chain exercises and balance/proprioceptive activities
- Perform lower extremity self-care and activities of daily living

#### Treatment:

- Progression exercises and addition of resistance bands/weights
- Introduce Weight machines as patient tolerate ( leg press, leg extension, hamstring curl within precautions)
- Closed chain strengthening exercises
- Static and dynamic balance and proprioceptive activities as appropriate
- Aquatic exercises as needed if incision completely healed
- Stationary bike
- Gait training ( using treadmill as appropriate)

#### Precautions

- Gradual progression to excessive/demanding activities within pain limits

#### Discharge Criteria:

- Reciprocal stairs climbing
- Independence in gait
- Return to sport or advanced activities of daily activities

#### Essential Implants and equipment's:

- SFDA approved Primary total hip replacement components including (femoral stem and head, an acetabular cup and liner)
- Walker



- ✓ Documented wide fluctuations in blood glucose before mealtime; or
- ✓ Documented dawn phenomenon (frequent early morning blood glucose increases) with fasting blood glucose frequently >200 mg/dL; or
- ✓ Documented history of severe glycaemic excursions.

Insulin pump therapy is recommended as a treatment option for **children younger than 12 years with T1DM** provided that:

1. MDI therapy is considered impractical or inappropriate; and
2. Children on insulin pumps would be expected to undergo a trial of MDI therapy.

**2.1.2 Ensuring appropriate composition of the healthcare professional team:**

Insulin pump therapy can be requested and initiated only by consultant endocrinologist or consultant diabetologist who manages multiple patients using insulin pumps and works closely with a highly trained specialist team, which should normally comprise nurses, diabetic educators, and dietitians who are knowledgeable in the use of insulin pumps.

