RMG

Data dictionary

(Revised on 15.06.2015)

MM - diagnostics

- Diagnostics
  - Followed-up as MGUS before (yes/no) *default*
  - MM/SMM diagnosis (yes/no)
  - History of solitary plasmacytoma (yes/no)
  - Polyneuropathy in medical history (yes/no)
  - Date of diagnosis (date) *default*
  - Status Performance (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
  - M-protein type (selection)
    - IgG
    - IgA
    - IgD
    - IgE
    - IgM
    - Biclonal
    - Triclonal
    - Nonsecretory
    - LC only
  - Serum monoclonal IgM protein quantity (g/l) (real number - scale: 1)
  - FLC quantity measured (yes/no) *default*
  - Serum lambda FLC quantity (mg/l) (real number - scale: 0)

- Serum kappa FLC quantity (mg/l) (real number - scale: 0)
- Kappa/lambda ratio (real number - scale: 0) *computed*
- Urine M-protein quantity (mg/24h) (real number - scale: 1)
- Light chain type (selection)
  - kappa
  - lambda
  - biclonal
- Bone marrow histology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count (%) (real number - scale: 0)
- Bone marrow aspiration cytology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count (%) (real number - scale: 0)
- Flow cytometry (yes/no)
- Normal PC - CD19 (%) (real number - scale: 1) *abs. min:0*
- Abnormal PC - CD56 (%) (real number - scale: 1) *abs. min:0*
- Normal/Abnormal (real number - scale: 2) *computed read-only*
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - can not evaluate
- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - can not evaluate
- Osteolytic lesions - CT (selection)

- ND
- negative
- 1 osteolytic lesion
- 2 osteolytic lesions
- more than 2 lesions
- can not evaluate

- Osteolytic lesions - PET (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - can not evaluate
- Osteolytic lesions - PET/CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - can not evaluate
- Osteolytic lesions - MIBI (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - can not evaluate
- Extramedullary mass (yes/no)
- Extramedullary mass - relation (selection)
  - extramedullary mass NOT related to bone
  - bone related extramedullary tumor mass
  - both tips
- Extramedullary mass histology (selection)
  - NA
  - negative

        - positive
    - Extramedullary masses count (selection)
        - 1
        - 2
        - 3
        - more than 3
    - Max size (cm) x (real number - scale: 0)
    - Max size (cm) y (real number - scale: 0)
    - Mass area (cm2) (real number - scale: 0) *computed*
- Biochemistry
    - Hemoglobin level (g/l) (real number - scale: 0)
    - Thrombocyte count (10E9/l) (real number - scale: 1)
    - Calcium total level (mmol/l) (real number - scale: 0)
    - Albumin level (g/l) (real number - scale: 0)
    - Creatinine level (umol/l) (real number - scale: 0)
    - Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
    - LDH (ukat/l) (real number - scale: 0)
    - CRP (mg/l) (real number - scale: 0)
    - Polyclonal IgG quantity (g/l) (real number - scale: 0)
    - Polyclonal IgA quantity (g/l) (real number - scale: 0)
    - Polyclonal IgM quantity (g/l) (real number - scale: 0)
    - Ig kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
    - Ig lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
    - HLC ratio (real number - scale: 2) *abs. min:0 computed read-only*
    - Cytogenetics (yes/no)
    - Date of sample collection (dd.mm.yyyy) (date)
    - IGH disruption (selection)
        - positive
        - negative
        - NA
- Cytogenetic - FISH
    - t(11;14) (selection)
        - positive
        - negative
        - NA

- t(11;14) (%) (real number - scale: 1)
- t(4;14) (selection)
  - positive
  - negative
  - NA
- t(4;14) (%) (real number - scale: 1)
- t(6;14) (selection)
  - positive
  - negative
  - NA
- t(6;14) (%) (real number - scale: 1)
- t(14;16) (selection)
  - positive
  - negative
  - NA
- t(14;16) (%) (real number - scale: 1)
- del(q14)/monosomy 13 (selection)
  - positive
  - negative
  - NA
- del(q14)/monosomy 13 (%) (real number - scale: 1)
- gain 1q21 (selection)
  - positive
  - negative
  - NA
- gain 1q21 (%) (real number - scale: 1)
- del(17)(p13) (selection)
  - positive
  - negative
  - NA
- del(17)(p13) (%) (real number - scale: 1)
- Hyperdiploidy (yes/no)

❖ <u>Stage</u>

- Durie-Salmon stage (selection) *computed*
  - I

        - II
        - III
    - Substage (selection) *computed*
        - A
        - B
    - High resolution Durie-Salmon stage (selection)
        - I
        - II
        - III
    - HR D-S based on (selection)
        - NMR
        - CT
        - PET
        - MIBI
        - PET/CT
    - ISS classification (selection) *computed*
        - Stage 1
        - Stage 2
        - Stage 3
- Amyloidosis at the time of diagnosis of MM

MM - treatment

- SMM
    - Progression SMM to MM (yes/no)
    - Date of progression (date)
- Reason for the start of the therapy
    - Calcium level increased: > 0.25 mmol/l above the upper limit of normal or > 2.75 mmol/l (yes/no)
    - Renal insufficiency: creatinine > 173 mmol/l (yes/no)
    - Anaemia: haemoglobin > 20 g/l below the lower limit of normal or < 100 g/l (yes/no)
    - Bone lesions: lytic lesions or osteoporosis with compression fractures (yes/no)
    - Other (yes/no)
    - Other specification (string)
- Primary treatment
    - Regimen (selection)
        - Without treatment

- Thalidomide based regimens
- Velcade based regimens
- Revlimid based regimens
- Other regimens
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid based regiment
- Carfilzomib based regimen
- Ixazomib based regimen

➢ Treatment modality - new (selection)

- Without treatment
- Thalidomide monotherapy
- TD (Thalidomide + Dexamethasone)
- TP (Thalidomide + Prednison)
- CTD junior therapy (Cyclophosphamide+Thalidomide+Dexamethasone)
- CTD senior therapy
- MPT junior therapy (Melphalan + Prednisone + Thalidomide)
- MPT senior therapy
- VTD therapy (Velcade + Thalidomide + Dexamethasone)
- CVTD therapy (Cyclophosphamide + Velcade + Thalidomide + Dexamethasone)
- CTD induction followed by Autologous stem cell transplantation
- CVTD induction followed by Autologous stem cell transplantation
- VTD induction followed by Autologous stem cell transplantation
- Other Thalidomide based combination
- Other Thalidomid based induction followed by Autologous stem cell transplantation
- TBD therapy (Thalidomide + Bendamustine + Dexamethasone)
- TBP therapy (Thalidomide + Bendamustine + Prednison)
- Velcade monotherapy
- VD therapy (Velcade - Dexamethasone)
- VP therapy (Velcade + Prednison)
- CVD junior therapy (Cyclophosphamide + Velcade + Dexamethasone)
- CVD senior therapy
- VMP junior therapy (Velcade + Melphalan + Prednison)
- VMP senior therapy

- BDD therapy (Velcade + Adriamycin + Dexamethasone)
- RVD therapy induction (Revlimide + Velcade + Dexamethasone)
- VD induction followed by Autologous stem cell transplantation
- CVD induction followed by Autologous stem cell transplantation
- BDD induction followed by Autologous stem cell transplantation
- Other Velcade based combination
- Other Velcade based induction followed by Autologous stem cell transplantation
- BBD therapy (Velcade + Bendamustine + Dexamethasone)
- BBP therapy (Velcade + Bendamustine + Prednison)
- Revlimid monotherapy
- RP junior therapy (Revlimide + Prednisone)
- RP senior therapy
- RD therapy (Revlimide + Dexamethasone)
- RCD junior therapy (Revlimide + Cyclophosphamide + Dexamethasone)
- RCD senior therapy
- RP induction followed by Autologous stem cell transplantation
- RD induction followed by Autologous stem cell transplantation
- RCD induction followed by Autologous stem cell transplantation
- RVD induction followed by Autologous stem cell transplantation
- Other Revlimid based combination
- Other Revlimid based induction followed by Autologous stem cell transplantation
- RAD junior therapy (Revlimid-Adriamycin+ Dexamethasone)
- RAD senior therapy
- RAD induction followed by Autologous stem cell transplantation
- RBD therapy (Revlimide + Bendamustine + Dexamethasone)
- RBP therapy (Revlimide + Bendamustine + Prednison)
- RCD therapy (Revlimid + Carfilzomib + Dexamethason)
- RID therapy (Revlimid + Ixazomib + Dexamethason)
- Corticosteroid monotherapy
- Melphalan monotherapy
- Cyclophosphamide monotherapy
- MP therapy (Melphalan + Prednison)
- CP therapy (Cyclophosphamide + Prednison)
- CD therapy (Cyclophosphamide + Dexamethasone)
- VAD therapy (Vincristin + Adriamycin + Dexamethasone)

- VID therapy (Vincristin + Idarubicin + Dexamethason)
- CAD junior therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- CAD senior therapy
- CED therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- VAD induction followed by Autologous stem cell transplantation
- VID induction followed by Autologous stem cell transplantation
- CAD induction followed by Autologous stem cell transplantation
- BD (Bendamustine + Dexamethazone)
- BP (Bendamustine + Prednison)
- Bendamustin monotherapy
- Other
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid monotherapy
- Imnovid + Dexamethasone
- Other Imnovid based combination
- Carfilzomib monotherapy
- CD Therapy (Carfilzomib + Dexamethasone)
- CMP therapy (Carfilzomib + Melphalan + Prednison)
- Other Carfilzomid based combination
- Ixazomib monotherapy
- ID therapy (Ixazomib + Dexamethasone)
- LID therapy (Ixazomib + Lenalidomid + Dexamethasone)
- IMP therapy (Ixazomib + Melphalan + Prednison)
- Other Ixazomib based combination

- Specify other treatment (string)
- Switch of therapy regimen (yes/no)
- Reason for switch (string)
- Regimen (selection)
  - Without treatment
  - Thalidomide based regimens
  - Velcade based regimens
  - Revlimid based regimens
  - Other regimens

- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid based regiment
- Carfilzomib based regimen
- Ixazomib based regimen

➢ Switch to (selection)

- Without treatment
- Thalidomide monotherapy
- TD (Thalidomide + Dexamethasone)
- TP (Thalidomide + Prednison)
- CTD junior therapy (Cyclophosphamide+Thalidomide+Dexamethasone)
- CTD senior therapy
- MPT junior therapy (Melphalan + Prednisone + Thalidomide)
- MPT senior therapy
- VTD therapy (Velcade + Thalidomide + Dexamethasone)
- CVTD therapy (Cyclophosphamide + Velcade + Thalidomide + Dexamethasone)
- CTD induction followed by Autologous stem cell transplantation
- CVTD induction followed by Autologous stem cell transplantation
- VTD induction followed by Autologous stem cell transplantation
- Other Thalidomide based combination
- Other Thalidomid based induction followed by Autologous stem cell transplantation
- TBD therapy (Thalidomide + Bendamustine + Dexamethasone)
- TBP therapy (Thalidomide + Bendamustine + Prednison)
- Velcade monotherapy
- VD therapy (Velcade - Dexamethasone)
- VP therapy (Velcade + Prednison)
- CVD junior therapy (Cyclophosphamide + Velcade + Dexamethasone)
- CVD senior therapy
- VMP junior therapy (Velcade + Melphalan + Prednison)
- VMP senior therapy
- BDD therapy (Velcade + Adriamycin + Dexamethasone)
- RVD therapy induction (Revlimide + Velcade + Dexamethasone)
- VD induction followed by Autologous stem cell transplantation
- CVD induction followed by Autologous stem cell transplantation

- BDD induction followed by Autologous stem cell transplantation
- Other Velcade based combination
- Other Velcade based induction followed by Autologous stem cell transplantation
- BBD therapy (Velcade + Bendamustine + Dexamethasone)
- BBP therapy (Velcade + Bendamustine + Prednison)
- Revlimid monotherapy
- RP junior therapy (Revlimide + Prednisone)
- RP senior therapy
- RD therapy (Revlimide + Dexamethasone)
- RCD junior therapy (Revlimide + Cyclophosphamide + Dexamethasone)
- RCD senior therapy
- RP induction followed by Autologous stem cell transplantation
- RD induction followed by Autologous stem cell transplantation
- RCD induction followed by Autologous stem cell transplantation
- RVD induction followed by Autologous stem cell transplantation
- Other Revlimid based combination
- Other Revlimid based induction followed by Autologous stem cell transplantation
- RAD junior therapy (Revlimid-Adriamycin+ Dexamethasone)
- RAD senior therapy
- RAD induction followed by Autologous stem cell transplantation
- RBD therapy (Revlimide + Bendamustine + Dexamethasone)
- RBP therapy (Revlimide + Bendamustine + Prednison)
- RCD therapy (Revlimid + Carfilzomib + Dexamethason)
- RID therapy (Revlimid + Ixazomib + Dexamethason)
- Corticosteroid monotherapy
- Melphalan monotherapy
- Cyclophosphamide monotherapy
- MP therapy (Melphalan + Prednison)
- CP therapy (Cyclophosphamide + Prednison)
- CD therapy (Cyclophosphamide + Dexamethasone)
- VAD therapy (Vincristin + Adriamycin + Dexamethasone)
- VID therapy (Vincristin + Idarubicin + Dexamethason)
- CAD junior therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- CAD senior therapy
- CED therapy (Cyclophosphamide + Etoposide + Dexamethasone)

- VAD induction followed by Autologous stem cell transplantation
- VID induction followed by Autologous stem cell transplantation
- CAD induction followed by Autologous stem cell transplantation
- BD (Bendamustine + Dexamethazone)
- BP (Bendamustine + Prednison)
- Bendamustin monotherapy
- Other
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid monotherapy
- Imnovid + Dexamethasone
- Other Imnovid based combination
- Carfilzomib monotherapy
- CD Therapy (Carfilzomib + Dexamethasone)
- CMP therapy (Carfilzomib + Melphalan + Prednison)
- Other Carfilzomid based combination
- Ixazomib monotherapy
- ID therapy (Ixazomib + Dexamethasone)
- LID therapy (Ixazomib + Lenalidomid + Dexamethasone)
- IMP therapy (Ixazomib + Melphalan + Prednison)
- Other Ixazomib based combination

- Radiotherapy (yes/no)
- Type of radiotherapy (selection)
  - analgetic
  - therapeutic
- Total dose [Gy] (number) *abs. min:0*
- Treatment beginning date (date) *abs. min:"1.1.1900"*
- Date of treatment withdrawal (date)
- Date of transplant (date) *abs. min:"1.1.1900"*
- Special transplantation technique (selection)
  - Tandem autotransplantation
  - Full - Allogenic transplantation
  - Mini - Allogenic transplantation
  - No

- Date of subsequent transplant (date) *abs. min:"1.1.1900"*
- Serum M-protein entry level (g/l) (real number - scale: 0) *abs.min:0*
- Urine M-protein entry level (mg/24h) (real number - scale: 0) *abs.min:0*
- Date of partial response (for DOR calculation) (date)
- Date of maximal final response to treatment (date)
- Serum M-protein level after treatment (g/l) (real number - scale: 0) *abs.min:0*
- Urine M-protein level after treatment (mg/24h) (real number - scale: 0) *abs.min:0*
- Serum M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs.min:0 computed*
- Urine M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs.min:0 computed*
- Immunofixation after treatment - serum (selection)
  - NA
  - negative
  - positive
- Immunofixation after treatment - urine (selection)
  - NA
  - negative
  - positive
- Plasmocyte count M (%) in bone marrow aspiration after treatment (real number - scale: 0)
- Kappa/lambda ratio (selection)
  - ND
  - normal
  - abnormal
- Final response to treatment - computed (string) *computed read-only*
- Do you agree with computed response? (yes/no) *default*
- Specify response (selection)
  - PG
  - SD
  - PR
  - VGPR
  - CR
  - sCR
  - MR
  - NA

- Explanation of the difference (string)
- Consolidation therapy (! except PBSCT) (yes/no)
- Maintenance therapy (yes/no)

❖ <u>Primary treatment adverse events</u>

- SAE (Serious Adverse Events) (yes/no)
- Description (long string)
- SUSAR (Suspect Serious Adverse Events) (yes/no)
- Description (long string)

❖ <u>Following treatment</u>

- Line of therapy (selection)
  - 2nd line
  - 3rd line
  - 4th line
  - 5th line
  - 6th line
  - 7th line
  - 8th line
  - 9th line
  - 10th line
  - 11th line
  - 12th line
  - 13th line
  - 14th line
  - 15th line
- Reason for treatment (selection)
  - relapse/progression
  - insufficient response
- Date of relapse/progression (date)
- Extramedullary mass (yes/no)
- Extramedullary mass - relation (selection)
  - extramedullary mass NOT related to bone
  - bone related extramedullary tumor mass
  - both tips
- Treatment beginning date (date)
- Date of treatment withdrawal (date)

- Treatment modality regimen (selection)
  - Without treatment
  - Thalidomide based regimens
  - Velcade based regimens
  - Revlimid based regimens
  - Other regimens
  - Other conventional chemotherapy
  - Other induction followed by Autologous stem cell transplantation
  - Salvage autologous transplantation technique
  - Imnovid based regiment
  - Carfilzomib based regimen
  - Ixazomib based regimen
- *Treatment modality new (selection)
  - Without treatment
  - Thalidomide monotherapy
  - TD (Thalidomide + Dexamethasone)
  - TP (Thalidomide + Prednison)
  - CTD junior therapy (Cyclophosphamide+Thalidomide+Dexamethasone)
  - CTD senior therapy
  - MPT junior therapy (Melphalan + Prednisone + Thalidomide)
  - MPT senior therapy
  - VTD therapy (Velcade + Thalidomide + Dexamethasone)
  - CVTD therapy (Cyclophosphamide + Velcade + Thalidomide + Dexamethasone)
  - CTD induction followed by Autologous stem cell transplantation
  - CVTD induction followed by Autologous stem cell transplantation
  - VTD induction followed by Autologous stem cell transplantation
  - Other Thalidomide based combination
  - Other Thalidomid based induction followed by Autologous stem cell transplantation
  - TBD therapy (Thalidomide + Bendamustine + Dexamethasone)
  - TBP therapy (Thalidomide + Bendamustine + Prednison)
  - Velcade monotherapy
  - VD therapy (Velcade - Dexamethasone)
  - VP therapy (Velcade + Prednison)
  - CVD junior therapy (Cyclophosphamide + Velcade + Dexamethasone)
  - CVD senior therapy

- VMP junior therapy (Velcade + Melphalan + Prednison)
- VMP senior therapy
- BDD therapy (Velcade + Adriamycin + Dexamethasone)
- RVD therapy induction (Revlimide + Velcade + Dexamethasone)
- VD induction followed by Autologous stem cell transplantation
- CVD induction followed by Autologous stem cell transplantation
- BDD induction followed by Autologous stem cell transplantation
- Other Velcade based combination
- Other Velcade based induction followed by Autologous stem cell transplantation
- BBD therapy (Velcade + Bendamustine + Dexamethasone)
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- Revlimid monotherapy
- RP junior therapy (Revlimide + Prednisone)
- RP senior therapy
- RD therapy (Revlimide + Dexamethasone)
- RCD junior therapy (Revlimide + Cyclophosphamide + Dexamethasone)
- RCD senior therapy
- RP induction followed by Autologous stem cell transplantation
- RD induction followed by Autologous stem cell transplantation
- RCD induction followed by Autologous stem cell transplantation
- RVD induction followed by Autologous stem cell transplantation
- Other Revlimid based combination
- Other Revlimid based induction followed by Autologous stem cell transplantation
- RAD junior therapy (Revlimid-Adriamycin+ Dexamethasone)
- RAD senior therapy
- RAD induction followed by Autologous stem cell transplantation
- RBD therapy (Revlimide + Bendamustine + Dexamethasone)
- RBP therapy (Revlimide + Bendamustine + Prednison)
- RCD therapy (Revlimid + Carfilzomib + Dexamethason)
- RID therapy (Revlimid + Ixazomib + Dexamethason)
- Corticosteroid monotherapy
- Melphalan monotherapy
- Cyclophosphamide monotherapy
- MP therapy (Melphalan + Prednison)
- CP therapy (Cyclophosphamide + Prednison)

- CD therapy (Cyclophosphamide + Dexamethasone)
- VAD therapy (Vincristin + Adriamycin + Dexamethasone)
- VID therapy (Vincristin + Idarubicin + Dexamethason)
- CAD junior therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- CAD senior therapy
- CED therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- VAD induction followed by Autologous stem cell transplantation
- VID induction followed by Autologous stem cell transplantation
- CAD induction followed by Autologous stem cell transplantation
- BD (Bendamustine + Dexamethazone)
- BP (Bendamustine + Prednison)
- Bendamustin monotherapy
- Other
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid monotherapy
- Imnovid + Dexamethasonea
- Other Imnovid based combination
- Carfilzomib monotherapy
- CD Therapy (Carfilzomib + Dexamethasone)
- CMP therapy (Carfilzomib + Melphalan + Prednison)
- Other Carfilzomid based combination
- Ixazomib monotherapy
- ID therapy (Ixazomib + Dexamethasone)
- LID therapy (Ixazomib + Lenalidomid + Dexamethasone)
- IMP therapy (Ixazomib + Melphalan + Prednison)
- Other Ixazomib based combination

- Specify other treatment (string)
- Switch of therapy regimen (yes/no)
- Reason for switch (string)
- Switch to regimen (selection)
  - Without treatment
  - Thalidomide based regimens
  - Velcade based regimens

- Revlimid based regimens
- Other regimens
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid based regiment
- Carfilzomib based regimen
- Ixazomib based regimen

➢ Switch to (selection)

- Without treatment
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- VTD therapy (Velcade + Thalidomide + Dexamethasone)
- CVTD therapy (Cyclophosphamide + Velcade + Thalidomide + Dexamethasone)
- CTD induction followed by Autologous stem cell transplantation
- CVTD induction followed by Autologous stem cell transplantation
- VTD induction followed by Autologous stem cell transplantation
- Other Thalidomide based combination
- Other Thalidomid based induction followed by Autologous stem cell transplantation
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- TBP therapy (Thalidomide + Bendamustine + Prednison)
- Velcade monotherapy
- VD therapy (Velcade - Dexamethasone)
- VP therapy (Velcade + Prednison)
- CVD junior therapy (Cyclophosphamide + Velcade + Dexamethasone)
- CVD senior therapy
- VMP junior therapy (Velcade + Melphalan + Prednison)
- VMP senior therapy
- BDD therapy (Velcade + Adriamycin + Dexamethasone)
- RVD therapy induction (Revlimide + Velcade + Dexamethasone)

- VD induction followed by Autologous stem cell transplantation
- CVD induction followed by Autologous stem cell transplantation
- BDD induction followed by Autologous stem cell transplantation
- Other Velcade based combination
- Other Velcade based induction followed by Autologous stem cell transplantation
- BBD therapy (Velcade + Bendamustine + Dexamethasone)
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- VID therapy (Vincristin + Idarubicin + Dexamethason)
- CAD junior therapy (Cyclophosphamide + Etoposide + Dexamethasone)

- CAD senior therapy
- CED therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- VAD induction followed by Autologous stem cell transplantation
- VID induction followed by Autologous stem cell transplantation
- CAD induction followed by Autologous stem cell transplantation
- BD (Bendamustine + Dexamethazone)
- BP (Bendamustine + Prednison)
- Bendamustin monotherapy
- Other
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid monotherapy
- Imnovid + Dexamethasone
- Other Imnovid based combination
- Carfilzomib monotherapy
- CD Therapy (Carfilzomib + Dexamethasone)
- CMP therapy (Carfilzomib + Melphalan + Prednison)
- Other Carfilzomid based combination
- Ixazomib monotherapy
- ID therapy (Ixazomib + Dexamethasone)
- LID therapy (Ixazomib + Lenalidomid + Dexamethasone)
- IMP therapy (Ixazomib + Melphalan + Prednison)
- Other Ixazomib based combination

- Radiotherapy (yes/no)
- Type of radiotherapy (selection)
  - analgetic
  - therapeutic
- Total dose [Gy] (number) *abs. min:0*
- Date of maximal final response (date)
- *Final response to treatment (selection)
  - PG
  - SD
  - PR
  - VGPR

        - CR
        - sCR
        - MR
        - NA
    - Date of partial response (for DOR calculation) (date)
    - Consolidation therapy (yes/no)
    - Maintenance therapy (yes/no)
    - SAE (yes/no)
    - Specify SAE (string)
    - SUSAR (yes/no)
    - Specify SUSAR (string)
    - PFS (number)
    - TTP (number)
    - DFS (number)
    - DOR (number)
- Follow-up
    - Date of evaluation (date)
    - Patient (selection)
        - unknown
        - alive
        - dead
    - Patient status (selection)
        - unknown
        - treated
        - not treated
- Amyloidosis with MM
- Death
    - Date of death (date)
    - Cause of death (selection)
        - related to diagnosis
        - other
        - related to Bisphosphonate treatment
    - Note (long string)
    - OS (number) *computed read-only*
    - Date of diagnosis (date) *default read-only*

Primary treatment - extension

- Biochemistry before treatment
  - Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
  - Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
  - Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
  - Albumin level (g/l) (real number - scale: 0) *abs. min:0*
  - Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*
  - Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
  - LDH (ukat/l) (real number - scale: 0) *abs. min:0*
  - CRP (mg/l) (real number - scale: 0) *abs. min:0*
- Before treatment
  - Status Performance (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
  - Karnofsky status (selection)
    - NA
    - 10
    - 20
    - 30
    - 40
    - 50
    - 60
    - 70
    - 80
    - 90
    - 100
  - Durie-Salmon stage (selection)
    - I
    - II
    - III

- Substage (selection) *computed*
  - A
  - B
- ISS classification (selection) *computed*
  - Stage 1
  - Stage 2
  - Stage 3
- Change of M-protein type? (yes/no)
- M-protein type (selection)
  - IgG
  - IgA
  - IgD
  - IgE
  - IgM
  - Biclonal
  - Triclonal
  - Nonsecretory
  - LC only
- Light chain type (selection)
  - kappa
  - lambda
  - biclonal
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions

- accelerated osteoporosis
- can not evaluate

- Osteolytic lesions - CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET/CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - MIBI (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Extramedullary mass (yes/no)

- Extramedullary mass - relation (selection)
  - extramedullary mass NOT related to bone
  - bone related extramedullary tumor mass
  - both tips
- Extramedullary mass histology (selection)
  - NA
  - negative
  - positive
- Extramedullary masses count (selection)
  - 1
  - 2
  - 3
  - more than 3
- Max size (cm) x (real number - scale: 0) *abs.min:0*
- Max size (cm) y (real number - scale: 0) *abs.min:0*
- Mass area (cm2) (real number - scale: 0) *abs.min:0 computed*
- Bone marrow aspiration cytology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs.min:0 abs.max:100*
- Bone marrow histology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs.min:0 abs.max:100*

❖ <u>Cytogenetics (FISH) before treatment</u>

- Cytogenetics (yes/no)
- Sample date (date) *abs.min:"1.1.1900"*

❖ <u>Treatment</u>

- Drug (selection)
  - Thalidomid
  - Velcade
  - Revlimid
  - Bendamustin

- Imnovid
- Carfilzomib
- Ixazomib

- Combined with (selection)
  - No
  - Thalidomid
  - Velcade
  - Revlimid
  - Bendamustin
  - Imnovid
  - Carfilzomib
  - Ixazomib
- Health insurance company (selection)
  - 111 - Všeobecná zdravotní pojišťovna
  - 201 - Vojenská zdravotní pojišťovna
  - 205 - Česká průmyslová zdravotní pojišťovna
  - 207 - Oborová pojišťovna zaměstnanců bank, pojišťoven a stavebnictví
  - 209 - Zaměstnanecká pojišťovna Škoda
  - 211 - Zdravotní pojišťovna Ministerstva vnitra ČR
  - 213 - Revírní bratrská pokladna
  - 217 - Zdravotní pojišťovna METAL-ALIANCE - do 1.10.2012
  - 222 - Česká národní zdravotní pojišťovna - do 1.10.2009
  - 227 - AGEL - do 1.7.2009
  - 228 - MÉDIA - do 28.3.2011
  - 999 - Není pojištěncem české ZP
- Clinical study (yes/no)
- Length of cycle (number) *abs.min:0*
- Dosage of the first administration (mg) (real number - scale: 2) *abs.min:0*
- Dosage of the first administration (mg/m2) (real number - scale: 2) *abs.min:0*
- Route of administration (selection)
  - Only subcutaneous
  - Only intravenous
  - Subcutaneous and change to intravenous
  - Intravenous and change to subcutaneous
- Number of administrations per cycle (number) *abs.min:0*

- Number of cycles (real number - scale: 2) *abs.min:0*
- Total number of administrations (number) *abs.min:0*
- Total cumulative dose (mg) (real number - scale: 2) *abs.min:0*

❖ <u>Second drug for drug combination (for switch data see section below)</u>

- Dosage of the first administration (mg) - second drug (real number - scale: 2) *abs. min:0*
- Dosage of the first administration (mg/m2) - second drug (real number - scale: 2) *abs. min:0*
- Route of administration – second drug (selection)
  - Only subcutaneous
  - Only intravenous
  - Subcutaneous and change to intravenous
  - Intravenous and change to subcutaneous
- Number of administrations per cycle - second drug (number) *abs. min:0*
- Total number of administrations - second drug (number) *abs. min:0*
- Total cumulative dose (mg) - second drug (real number - scale: 2) *abs. min:0*
- Reason for treatment withdrawal (selection)
  - Treatment response
  - Treatment response + PBSCT (transplantation)
  - According treatment protocol
  - Insufficient response
  - Progression
  - Toxicity
  - Exitus
  - Other
- Specify other reason (string)
- MR after cycle (number) *abs. min:0*
- Date of MR (date) *abs. min:"1.1.1900"*
- PR after cycle (number) *abs. min:0*
- Date of PR (date) *abs. min:"1.1.1900"*
- VGPR after cycle (number) *abs. min:0*
- Date of VGPR (date) *abs. min:"1.1.1900"*
- CR after cycle (number) *abs. min:0*
- Date of CR (date) *abs. min:"1.1.1900"*
- Response before transplant (selection)
  - PG

        - SD
        - PR
        - VGPR
        - CR
        - sCR
        - MR
        - NA
    - Dose reduction (yes/no)
    - Interruption of treatment (yes/no)
- <u>Dose reduction</u>
    - Reduction number (selection)
        - 1st
        - 2nd
        - 3rd
        - 4th
        - 5th
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
    - 1st reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia

    - Anemia
    - other
- Specify other (string)
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 2nd reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea
    - Constipation
    - Fatigue
    - Thrombosis/thrombus/Embolism
    - Infection
    - Thrombocytopenia
    - Neutropenia
    - Anemia
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 3rd reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea
    - Constipation

        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - New dosage (mg) (real number - scale: 2) *abs. min:0*
    - New dosage (mg/m2) (real number - scale: 2) *abs. min:0*
- <u>Interruption of treatment</u>
    - Interruption number (selection)
        - 1st
        - 2nd
        - 3rd
        - 4th
        - 5th
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
        - All
    - 1st reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia

    - Diarrhoea
    - Constipation
    - Fatigue
    - Thrombosis/thrombus/Embolism
    - Infection
    - Thrombocytopenia
    - Neutropenia
    - Anemia
    - other
- Specify other (string)
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 2nd reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea
    - Constipation
    - Fatigue
    - Thrombosis/thrombus/Embolism
    - Infection
    - Thrombocytopenia
    - Neutropenia
    - Anemia
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4

        - 5
    - 3rd reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
- Toxicity
- Toxicity before treatment
    - Grade of thrombocytopenia before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
    - Grade of neuropathy before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
- Toxicity during treatment

- Neuropathy - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Nausea, vomiting - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Anorexia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Diarrhoea - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Constipation - grade (selection)
  - 0
  - 1

- 2
- 3
- 4
- 5
- ND

- Fatigue - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Thrombosis/thrombus/Embolism - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Infection - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Thrombocytopenia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4

    - 5
    - ND
- Neutropenia - grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
    - ND
- Anemia - grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
    - ND
- Other - text (string)
- Other - grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- Other 2 - text (string)
- Other 2 - grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- Switch of treatment due to toxicity (yes/no)

- Anticoagulant treatment
  - Anticoagulant treatment (yes/no)
  - Type of anticoagulant treatment (selection)
    - aspirin
    - warfarin
    - LMWH
    - other
  - Specify anticoagulant treatment (string)
- Hemopoetic growth factor
  - Hemopoetic growth factor (yes/no)
  - Dosage 30 IU / 0,5ml - number of doses (number) *default abs. min:0*
  - Dosage 48 IU/0,5 ml - number of doses (number) *default abs. min:0*
- Switch of therapy
- Consolidation treatment
  - Consolidation treatment (! except PBSCT) (yes/no)
  - Specify consolidation treatment (selection)
    - bortezomid based
    - thalidomid based
    - lenalidomid based
    - other
  - Specify other treatment (string)
  - Date of treatment beginning (date) *abs. min:"1.1.1900"*
  - Date of treatment withdrawal (date) *abs. min:"1.1.1900"*
  - Reason for treatment withdrawal (selection)
    - Treatment response
    - Treatment response + PBSCT (transplantation)
    - According treatment protocol
    - Insufficient response
    - Progression
    - Toxicity
    - Exitus
    - Other
  - Number of cycles (real number - scale: 2) *abs. min:0*
  - Maximal response (selection)
    - PG

- SD
- PR
- VGPR
- CR
- sCR
- MR

❖ Consolidation treatment - adverse events

- Toxicity (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
  - other
- Specify other (string)
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5

❖ Maintenance therapy

- Maintenance therapy (yes/no)
- Specify maintenance therapy (selection)
  - intereferon
  - prednison
  - bortezomid 1 x week
  - chemotherapy

        - lenalidomide 10
        - thalidomid 50
        - thalidomid 100
        - lenalidomide/prednison
        - other
    - Specify other treatment (string)
    - Treatment beginning date (date) *abs. min:"1.1.1900"*
    - Date of treatment withdrawal (date) *abs. min:"1.1.1900"*
    - Reason for treatment withdrawal (selection)
        - Treatment response
        - Treatment response + PBSCT (transplantation)
        - According treatment protocol
        - Insufficient response
        - Progression
        - Toxicity
        - Exitus
        - Other
    - Maximal response (selection)
        - PG
        - SD
        - PR
        - VGPR
        - CR
        - sCR
        - MR
- <u>Maintenance therapy - adverse events</u>
    - Toxicity (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection

        - Thrombocytopenia
        - Neutropenia
        - Anemia
        - other
    - Specify other (string)
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
- Comments
    - Comments (long string)

Following treatment - extension

- Line of therapy
    - Line of therapy (selection)
        - 2nd line
        - 3rd line
        - 4th line
        - 5th line
        - 6th line
        - 7th line
        - 8th line
        - 9th line
        - 10th line
        - 11th line
        - 12th line
        - 13th line
        - 14th line
        - 15th line
- Reason for the start of the therapy
    - Calcium level increased: > 0.25 mmol/l above the upper limit of normal or > 2.75 mmol/l (yes/no)
    - Renal insufficiency: creatinine > 173 mmol/l (yes/no)

- Anaemia: haemoglobin > 20 g/l below the lower limit of normal or < 100 g/l (yes/no)
- Bone lesions: lytic lesions or osteoporosis with compression fractures (yes/no)
- Other (yes/no)
- Other specification (string)

❖ Biochemistry before treatment

- Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
- Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
- Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
- Albumin level (g/l) (real number - scale: 0) *abs. min:0*
- Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*
- Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
- LDH (ukat/l) (real number - scale: 0) *abs. min:0*
- CRP (mg/l) (real number - scale: 0) *abs. min:0*

❖ <u>Before treatment</u>

- Status Performance (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
- Karnofsky status (selection)
  - NA
  - 10
  - 20
  - 30
  - 40
  - 50
  - 60
  - 70
  - 80
  - 90
  - 100
- Durie-Salmon stage (selection)
  - I
  - II

- III

- Substage (selection) *computed*
  - A
  - B
- ISS classification (selection) *computed*
  - Stage 1
  - Stage 2
  - Stage 3
- Change of M-protein type? (yes/no)
- M-protein type (selection)
  - IgG
  - IgA
  - IgD
  - IgE
  - IgM
  - Biclonal
  - Triclonal
  - Nonsecretory
  - LC only
- Light chain type (selection)
  - kappa
  - lambda
  - biclonal
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions

- more than 2 lesions
- accelerated osteoporosis
- can not evaluate

- Osteolytic lesions - CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET/CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - MIBI (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate

- Extramedullary mass (yes/no)
- Extramedullary mass - relation (selection)
  - extramedullary mass NOT related to bone
  - bone related extramedullary tumor mass
  - both tips
- Extramedullary mass histology (selection)
  - NA
  - negative
  - positive
- Extramedullary masses count (selection)
  - 1
  - 2
  - 3
  - more than 3
- Max size (cm) x (real number - scale: 0) *abs. min:0*
- Max size (cm) y (real number - scale: 0) *abs. min:0*
- Mass area (cm2) (real number - scale: 0) *abs. min:0 computed*
- Serum M-protein entry level (g/l) (real number - scale: 0) *abs. min:0*
- Urine M-protein entry level (mg/24h) (real number - scale: 0) *abs. min:0*
- Bone marrow aspiration cytology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*
- Bone marrow histology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*

❖ <u>Cytogenetics before treatment</u>

- Cytogenetics (yes/no)
- Sample date (date) *abs. min:"1.1.1900"*

❖ <u>Treatment</u>

- Drug (selection)
  - Thalidomid

- Velcade
- Revlimid
- Bendamustin
- Imnovid
- Carfilzomib
- Ixazomib

- Combined with (selection)
  - No
  - Thalidomid
  - Velcade
  - Revlimid
  - Bendamustin
  - Imnovid
  - Carfilzomib
  - Ixazomib
- Health insurance company (selection)
  - 111 - Všeobecná zdravotní pojišťovna
  - 201 - Vojenská zdravotní pojišťovna
  - 205 - Česká průmyslová zdravotní pojišťovna
  - 207 - Oborová pojišťovna zaměstnanců bank, pojišťoven a stavebnictví
  - 209 - Zaměstnanecká pojišťovna Škoda
  - 211 - Zdravotní pojišťovna Ministerstva vnitra ČR
  - 213 - Revírní bratrská pokladna
  - 217 - Zdravotní pojišťovna METAL-ALIANCE - do 1.10.2012
  - 222 - Česká národní zdravotní pojišťovna - do 1.10.2009
  - 227 - AGEL - do 1.7.2009
  - 228 - MÉDIA - do 28.3.2011
  - 999 - Není pojištěncem české ZP
- Clinical study (yes/no)
- Date of transplant (date)
- Special transplantation technique (selection)
  - Tandem autotransplantation
  - Full - Allogenic transplantation
  - Mini - Allogenic transplantation
  - No

- Date of subsequent transplant (date) *abs. min:"1.1.1900"*
- Length of cycle (number) *abs. min:0*
- Dosage of the first administration (mg) (real number - scale: 2) *abs. min:0*
- Dosage of the first administration (mg/m2) (real number - scale: 2) *abs. min:0*
- Route of administration (selection)
  - Only subcutaneous
  - Only intravenous
  - Subcutaneous and change to intravenous
  - Intravenous and change to subcutaneous
- Number of administrations per cycle (number) *abs. min:0*
- Number of cycles (real number - scale: 2) *abs. min:0*
- Total number of administrations (number) *abs. min:0*
- Total cumulative dose (mg) (real number - scale: 2) *abs. min:0*

❖ <u>Second drug - for combinated treatment only</u>

- Dosage of the first administration (mg) - second drug (real number - scale: 2) *abs. min:0*
- Dosage of the first administration (mg/m2) - second drug (real number - scale: 2) *abs. min:0*
- Route of administration (selection)
  - Only subcutaneous
  - Only intravenous
  - Subcutaneous and change to intravenous
  - Intravenous and change to subcutaneous
- Number of administrations per cycle - second drug (number)
- Total number of administrations - second drug (number) *abs. min:0*
- Total cumulative dose (mg) - second drug (real number - scale: 2) *abs. min:0*
- Reason for treatment withdrawal (selection)
  - Treatment response
  - Treatment response + PBSCT (transplantation)
  - According treatment protocol
  - Insufficient response
  - Progression
  - Toxicity
  - Exitus
  - Other
- Specify other reason (string)

- Serum M-protein level after treatment (g/l) (real number - scale: 0) *abs. min:0*
- Urine M-protein level after treatment (mg/24h) (real number - scale: 0) *abs. min:0*
- Serum M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
- Urine M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
- Immunofixation after treatment - serum (selection)
  - NA
  - negative
  - positive
- Immunofixation after treatment - urine (selection)
  - NA
  - negative
  - positive
- MR after cycle (number) *abs. min:0*
- Date of MR (date) *abs. min:"1.1.1900"*
- PR after cycle (number) *abs. min:0*
- Date of PR (date) *abs. min:"1.1.1900"*
- VGPR after cycle (number) *abs. min:0*
- Date of VGPR (date) *abs. min:"1.1.1900"*
- CR after cycle (number) *abs. min:0*
- Date of CR (date) *abs. min:"1.1.1900"*
- Response before transplant (selection)
  - PG
  - SD
  - PR
  - VGPR
  - CR
  - sCR
  - MR
  - NA
- Dose reduction (yes/no)
- Interruption of treatment (yes/no)

❖ <u>Dose reduction</u>

- Reduction number (selection)
  - 1st

    - 2nd
    - 3rd
    - 4th
    - 5th
- Drug (selection)
    - Thalidomid
    - Velcade
    - Revlimid
    - Bendamustin
    - Imnovid
    - Carfilzomib
    - Ixazomib
- 1st reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea
    - Constipation
    - Fatigue
    - Thrombosis/thrombus/Embolism
    - Infection
    - Thrombocytopenia
    - Neutropenia
    - Anemia
    - other
- Specify other (string)
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 2nd reason (selection)
    - Neuropathy

- Nausea, vomiting
- Anorexia
- Diarrhoea
- Constipation
- Fatigue
- Thrombosis/thrombus/Embolism
- Infection
- Thrombocytopenia
- Neutropenia
- Anemia

- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 3rd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4

- 5

- New dosage (mg) (real number - scale: 2) *abs. min:0*
- New dosage (mg/m2) (real number - scale: 2) *abs. min:0*

❖ <u>Interruption of treatment</u>

- Interruption number (selection)
  - 1st
  - 2nd
  - 3rd
  - 4th
  - 5th
- Drug (selection)
  - Thalidomid
  - Velcade
  - Revlimid
  - Bendamustin
  - Imnovid
  - Carfilzomib
  - Ixazomib
  - All
- 1st reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
  - other
- Specify other (string)
- Grade (selection)
  - 0

- 1
- 2
- 3
- 4
- 5

- 2nd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 3rd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia

        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5

- Toxicity
- Toxicity before treatment
    - Grade of thrombocytopenia before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
    - Grade of neuropathy before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
- Toxicity during treatment
    - Neuropathy - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
        - ND
    - Nausea, vomiting - grade (selection)
        - 0
        - 1
        - 2

- 3
- 4
- 5
- ND

- Anorexia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Diarrhoea - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Constipation - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Fatigue - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5

- ND

- Thrombosis/thrombus/Embolism - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Infection - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Thrombocytopenia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Neutropenia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Anemia - grade (selection)
  - 0

        - 1
        - 2
        - 3
        - 4
        - 5
        - ND
    - Other - text (string)
    - Other - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Other 2 - text (string)
    - Other 2 - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Switch of treatment due to toxicity (yes/no)
- <u>Anticoagulant treatment</u>
    - Anticoagulant treatment (yes/no)
    - Type of anticoagulant treatment (selection)
        - aspirin
        - warfarin
        - LMWH
        - other
    - Specify anticoagulant treatment (string)
- <u>Hemopoetic growth factor</u>
    - Hemopoetic growth factor (yes/no)
    - Dosage 30 IU / 0,5ml - number of doses (number) *default abs. min:0*
    - Dosage 48 IU/0,5 ml - number of doses (number) *default abs. min:0*

- Switch of therapy
- Consolidation treatment
  - Consolidation treatment (! except PBSCT) (yes/no)
  - Specify consolidation treatment (selection)
    - bortezomid based
    - thalidomid based
    - lenalidomid based
    - other
  - Specify other treatment (string)
  - Date of treatment beginning (date) *abs. min:"1.1.1900"*
  - Date of treatment withdrawal (date) *abs. min:"1.1.1900"*
  - Reason for treatment withdrawal (selection)
    - Treatment response
    - Treatment response + PBSCT (transplantation)
    - According treatment protocol
    - Insufficient response
    - Progression
    - Toxicity
    - Exitus
    - Other
  - Number of cycles (real number - scale: 2) *abs. min:0*
  - Maximal response (selection)
    - PG
    - SD
    - PR
    - VGPR
    - CR
    - sCR
    - MR
- Consolidation treatment - adverse events
  - Toxicity (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea

        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
        - other
    - Specify other (string)
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
- Maintenance therapy
    - Maintenance therapy (yes/no)
    - Specify maintenance therapy (selection)
        - intereferon
        - prednison
        - bortezomid 1 x week
        - chemotherapy
        - lenalidomide 10
        - thalidomid 50
        - thalidomid 100
        - lenalidomide/prednison
        - other
    - Specify other treatment (string)
    - Treatment beginning date (date) *abs. min:"1.1.1900"*
    - Date of treatment withdrawal (date) *abs. min:"1.1.1900"*
    - Reason for treatment withdrawal (selection)
        - Treatment response
        - Treatment response + PBSCT (transplantation)
        - According treatment protocol

        - Insufficient response
        - Progression
        - Toxicity
        - Exitus
        - Other
    - Maximal response (selection)
        - PG
        - SD
        - PR
        - VGPR
        - CR
        - sCR
        - MR

- Maintenance therapy - adverse events
    - Toxicity (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
        - other
    - Specify other (string)
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5

- Comments
  - Comments (long string)

MGUS

- Diagnostics
  - Date of diagnosis (date) *default*
  - Status Performance (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
  - M-protein type (selection)
    - IgG
    - IgA
    - IgD
    - IgE
    - IgM
    - Biclonal
    - Triclonal
    - Nonsecretory
    - LC only
  - Serum M-protein quantity (g/l) (real number - scale: 1)
  - FLC quantity measured (yes/no) *default*
  - Date of FLC measurement (date)
  - Serum kappa FLC quantity (mg/l) (real number - scale: 0)
  - Serum lambda FLC quantity (mg/l) (real number - scale: 0)
  - Kappa/lambda ratio (real number - scale: 0) *computed*
  - Urine M-protein quantity (mg/24h) (real number - scale: 1)
  - Light chain type (selection)
    - kappa
    - lambda
    - biclonal
  - Bone marrow aspiration cytology was done (yes/no)
  - Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*

- Bone marrow histology was done (yes/no)
- Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*
- Flow cytometry (yes/no)
- Plasmocyte count FC (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- CD19 poz B cell (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Normal PC - CD19 poz (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Abnormal PC - CD56 poz (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Abnormal PC - CD19 neg (real number - scale: 2) *computed read-only*
- Clonal PC (%) (number) *abs. min:0 abs. max:100*
- Polyclonal PC (%) (number) *computed read-only*
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET (selection)
  - ND

        - negative
        - 1 osteolytic lesion
        - 2 osteolytic lesions
        - more than 2 lesions
        - accelerated osteoporosis
        - can not evaluate
    - Osteolytic lesions - PET/CT (selection)
        - ND
        - negative
        - 1 osteolytic lesion
        - 2 osteolytic lesions
        - more than 2 lesions
        - accelerated osteoporosis
        - can not evaluate
    - Osteolytic lesions - MIBI (selection)
        - ND
        - negative
        - 1 osteolytic lesion
        - 2 osteolytic lesions
        - more than 2 lesions
        - accelerated osteoporosis
        - can not evaluate
- <u>Biochemistry</u>
    - Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
    - Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
    - Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
    - Albumin level (g/l) (real number - scale: 0) *abs. min:0*
    - Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*
    - Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
    - LDH (ukat/l) (real number - scale: 0) *abs. min:0*
    - CRP (mg/l) (real number - scale: 0) *abs. min:0*
    - Sample date (Polyclonal Ig) (date)
    - Polyclonal IgG quantity (g/l) (real number - scale: 0)
    - Polyclonal IgA quantity (g/l) (real number - scale: 0)
    - Polyclonal IgM quantity (g/l) (real number - scale: 0)

- Polyclonal IgE quantity (IU/ml) (real number - scale: 0)
- Date of sample collection (HLC) (date)
- Ig kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- Ig lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- HLC ratio (real number - scale: 2) *abs. min:0 computed read-only*
- Cytogenetics (yes/no)
- Date of sample collection (dd.mm.yyyy) (date)
- IGH disruption (selection)
  - positive
  - negative
  - NA
- t(11;14) (selection)
  - positive
  - negative
  - NA
- t(11;14) (%) (real number - scale: 1)
- t(4;14) (selection)
  - positive
  - negative
  - NA
- t(4;14) (%) (real number - scale: 1)
- t(6;14) (selection)
  - positive
  - negative
  - NA
- t(6;14) (%) (real number - scale: 1)
- t(14;16) (selection)
  - positive
  - negative
  - NA
- t(14;16) (%) (real number - scale: 1)
- del(13)(q14)/monosomy 13 (selection)
  - positive
  - negative
  - NA

- del(13)(q14)/monosomy 13 (%) (real number - scale: 1)
- gain 1q21 (selection)
  - positive
  - negative
  - NA
- gain 1q21 (%) (real number - scale: 1)
- del(17)(p13) (selection)
  - positive
  - negative
  - NA
- del(17)(p13) (%) (real number - scale: 1)
- Hyperdiploidy (yes/no)

❖ Molecular-biology

- Molecular-biology examination (yes/no)
- MYD88 examination (yes/no)
- Mutation in MYD88 gene (selection)
  - negative
  - L265P
- CXCR4 examination (yes/no)
- Mutation in CXCR4 gene (selection)
  - negative
  - nonsense
  - frameshift
- Specify mutation type in CXCR4 gene (string)

❖ Follow-up

- Date of evaluation (date)
- Serum M-protein quantity (real number - scale: 0)
- Associated disease (selection)
  - none
  - lymphoproliferative disorder
  - other hematological disease
  - connective tissue disorder
  - neurological disease
  - dermatological disease
  - endocrine disorder

        - liver disease
        - immunosupression
        - other
    - Further specification (string)
- MGUS development
    - Progression MGUS to (selection)
        - no progression
        - MM
        - WM
        - lymphoma
        - AL amyloidosis
        - CLL
        - plasmacytoma
        - other
    - Further specification (string)
    - Date of MGUS progression (date)
- Death
    - Patient (selection)
        - unknown
        - alive
        - dead
    - Date of death (date)
    - Cause of death (selection)
        - related to diagnosis
        - other
        - related to Bisphosphonate treatment
    - Note (long string)

Bisphosphonate and SRE treatment

- Skeleton X-ray
    - Date of examination (date)
    - Skull (selection)
        - no lesion
        - 1 osteolytic lesion
        - 2 osteolytic lesions

    - 3 and more lesions
    - diffuse osteoporosis
- Cervical spine (selection)
    - no lesion
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - 3 and more lesions
    - diffuse osteoporosis
- Thoracic spine (selection)
    - no lesion
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - 3 and more lesions
    - diffuse osteoporosis
- Lumbar spine (selection)
    - no lesion
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - 3 and more lesions
    - diffuse osteoporosis
- Humerus (selection)
    - no lesion
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - 3 and more lesions
    - diffuse osteoporosis
- Femur (selection)
    - no lesion
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - 3 and more lesions
    - diffuse osteoporosis
- Other localization (string)
- Result (selection)
    - no lesion

- 1 osteolytic lesion
- 2 osteolytic lesions
- 3 and more lesions
- diffuse osteoporosis

❖ Bisphosphonate treatment

- Date of beginning (date)
- Drug (selection)
  - clodronate - oral
  - clodronate - intravenous
  - pamidronate - intravenous
  - zolendronate - intravenous
  - ibandronate - intravenous
  - ibandronate - oral
- Dose (real number - scale: 0)
- Units (selection)
  - ug
  - mg
  - g
  - ul
  - ml
  - l
- Dosing (selection)
  - Every day
  - Every month
- Date of discontinuation (date)
- Reason for discontinuation (selection)
  - Toxicity
  - SRE
  - Other
- Specify other reason (string)
- Type of toxicity (selection)
  - Gastrointestinal
  - Renal
  - Osteonecrosis
  - Other

- Specify other toxicity (string)
- Is the event serious? (SAE) (yes/no)

❖ SRE

- SRE date (date)
- SRE type (selection)
  - New pathological fracture
  - Documented bone involment progression
  - Malignant hypercalcemia
  - Necessary surgical treatment of bone disease
  - Necessary radiotherapy of bone disease
- Progression extension (string)
- Progression confirmed (selection)
  - X-ray
  - MIBI scintigraphy
  - MRI
  - PET scan

WM - asymptomatic

❖ Diagnostics

- Followed up as MGUS (yes/no)
- Date of diagnosis asymptomatic Waldenstrőm's macroglobulinemia (date)
- Status Performance (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
- M-protein type (selection)
  - IgM Kappa
  - IgM Lambda
- Serum monoclonal IgM protein quantity (g/l) (real number - scale: 1)
- Serum FLC quantity measured (yes/no)
- Serum free lambda quantity (mg/l) (real number - scale: 0)
- Serum free kappa quantity (mg/l) (real number - scale: 0)
- Kappa/lambda ratio (real number - scale: 0) *computed*

- Urine M-protein quantity (mg/24h) (real number - scale: 1)

❖ <u>Polyclonal immunoglobuline quantitative estimation</u>

- IgM quantity (g/l) (real number - scale: 0)
- IgA quantity (g/l) (real number - scale: 0)
- IgG quantity (g/l) (real number - scale: 0)
- Date of sample collection (HLC) (date)
- Ig kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- Ig lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- HLC ratio (real number - scale: 2) *abs. min:0 computed read-only*
- Bone marrow histology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocytic, lymphoplasmocytic and lymphocytic cells in bone marrow (%) (real number - scale: 0)
- Bone marrow aspiration cytology (selection)
  - NOT DONE
  - negative
  - positive
- Plasmocytic, lymphoplasmocytic and lymphocytic cells in bone marrow smears (%) (real number - scale: 0)
- Flow cytometry (yes/no)
- CD19 poz B cell (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal B cell (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Lymphoplasmocytic cells (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal lymphoplasmocytic cells (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Plasmocyte count FC (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal PC (%) (number) *abs. min:0 abs. max:100*
- Bone X ray - osteolytic lesions (X ray) (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate

- MR examination
  - MR examination of bones (selection)
    - ND
    - Negative
    - Positive
- CT examination
  - Mediastinal and abdominal CT examination (yes/no)
  - Lymphadenopathy cervical (yes/no)
  - Lymphadenopathy thoracic (yes/no)
  - Lymphadenopathy axillar (yes/no)
  - Lymphadenopathy abdominal (yes/no)
  - Lymphadenopathy inguinal (yes/no)
  - Splenomegaly (yes/no)
  - Hepatomegaly (yes/no)
  - Extralymphatic and extraosseal tissue infiltration or pathologic mass (yes/no)
- Sonographic examination
  - Sonographic examination (yes/no)
  - Lymphadenopathy inguinal (yes/no)
  - Lymphadenopathy abdominal (yes/no)
  - Lymphadenopathy axillar (yes/no)
  - Lymphadenopathy cervical (neck) (yes/no)
  - Splenomegaly (yes/no)
  - Hepatomegaly (yes/no)
- FDG-PET
  - FDG-PET (CT) activity (selection)
    - ND
    - negative
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - more than 2 lesions
    - accelerated osteoporosis
  - Abdominal nodal or extranodal activity (yes/no)
  - Thoracic nodal or extranodal activity (yes/no)
  - Extraabdominal and extrathoracic activity (yes/no)
- Laboratory analysis

- Hemoglobin level (g/l) (real number - scale: 0) *abs.min:0*
- Thrombocyte count (10E9/l) (real number - scale: 1) *abs.min:0*
- Leukocyte count (10E9/l) (real number - scale: 0)
- Neutrofil count (10E9/l) (real number - scale: 0)
- Calcium total level (mmol/l) (real number - scale: 0) *abs.min:0*
- Albumin level (g/l) (real number - scale: 0) *abs.min:0*
- Total protein (g/l) (real number - scale: 0)
- Creatinine level (umol/l) (real number - scale: 0) *abs.min:0*
- Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
- LDH (ukat/l) (real number - scale: 0) *abs.min:0*
- Upper normal value of LDH (ukat/l) (real number - scale: 0)
- LDH/upper normal value of LDH (real number - scale: 2) *computed*
- CRP (mg/l) (real number - scale: 0) *abs.min:0*
- Cholesterol (mmol/l) (real number - scale: 2)

❖ Cytogenetic

❖ Cytogenetic

- Cytogenetic examination (yes/no)
- Del 6q (yes/no)
- Del 6q (%) (real number - scale: 0)
- Translocation on chromosome 14, locus IgH (yes/no)

❖ Molecular-biology

- Molecular-biology examination (yes/no)
- MYD88 examination (yes/no)
- Mutation in MYD88 gene (selection)
  - negative
  - L265P
- CXCR4 examination (yes/no)
- Mutation in CXCR4 gene (selection)
  - negative
  - nonsense
  - frameshift
- Specify mutation type in CXCR4 gene (string)

❖ WM development

- Progression asymptomatic WM (selection)
  - no progression

        - symptomatic WM
    - Date of progression (date)
- Death
    - Patient (selection)
        - unknown
        - alive
        - dead
    - Date of death (date)
    - Cause of death (selection)
        - related to diagnosis
        - other
        - related to Bisphosphonate treatment
    - Note (long string)

WM - symptomatic

- WM - symptomatic
    - Date of diagnosis symptomatic Waldenstrőm's macroglobulinemia (date)
    - Previous history of asymptomatic WM (yes/no)
    - Previous history of asymptomatic WM from year (number) *abs. min:1900*
    - Previous history of IgM gammopathy (yes/no)
    - Previous history of IgM gammopathy from year (number) *abs. min:1900*
    - Status Performance (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
- Clinical symptoms
    - Clinical symptoms of hyperviskosity (selection)
        - unknown
        - no
        - yes
    - Clinical symptoms of cryoglobulinaemia (selection)
        - unknown
        - no

- yes

- Clinical symptoms of neuropathy (selection)
  - unknown
  - no
  - yes
- Symptoms of cold aglutinins (selection)
  - unknown
  - no
  - yes
- Clinical symptoms of AK-amyloidosis (selection)
  - unknown
  - no
  - yes
- Clinical symptoms of nephropathy (selection)
  - unknown
  - no
  - yes
- B symptoms (selection)
  - unknown
  - no
  - yes
- Night sweats (selection)
  - unknown
  - no
  - yes
- Subfebrile and febrile of unknown origin (selection)
  - unknown
  - no
  - yes
- Weight loss moe then 10% in 6 month (selection)
  - unknown
  - no
  - yes
- Hepato-splenomegaly (selection)
  - unknown

        - no
        - yes
    - Organomegaly (selection)
        - unknown
        - no
        - yes
    - Malignant osteolysis (selection)
        - unknown
        - no
        - yes
    - Other (selection)
        - unknown
        - no
        - yes
    - Other specification (string)

❖ <u>Bone marrow examination</u>

- Bone marrow histology (selection)
    - NOT DONE
    - negative
    - positive
- Plasmocytic, lymphoplasmocytic and lymphocytic cells in bone marrow (%) (real number - scale: 0)
- Bone marrow aspiration cytology (selection)
    - NOT DONE
    - negative
    - positive
- Plasmocytic, lymphoplasmocytic and lymphocytic cells in bone marrow smears (%) (real number - scale: 0)
- Flow cytometry (yes/no)
- CD19 poz B cell (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal B cell (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Lymphoplasmocytic cells (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal lymphoplasmocytic cells (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Plasmocyte count FC (%) (real number - scale: 1) *abs. min:0 abs. max:100*
- Clonal PC (%) (number) *abs. min:0 abs. max:100*

❖ <u>Imaging methods before therapy</u>

- Bone X ray - osteolytic lesions (X ray) (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate

❖ Sonographic examination

- Sonographic examination (yes/no)
- Lymphadenopathy inguinal (yes/no)
- Lymphadenopathy abdominal (yes/no)
- Lymphadenopathy axillar (yes/no)
- Lymphadenopathy cervical (neck) (yes/no)
- Splenomegaly (yes/no)
- Hepatomegaly (yes/no)

❖ MR examination

- MR examination of bones (selection)
  - ND
  - Negative
  - Positive

❖ CT examination

- Mediastinal and abdominal CT examination (yes/no)
- Lymphadenopathy cervical (yes/no)
- Lymphadenopathy thoracic (yes/no)
- Lymphadenopathy axillar (yes/no)
- Lymphadenopathy abdominal (yes/no)
- Lymphadenopathy inguinal (yes/no)
- Splenomegaly (yes/no)
- Hepatomegaly (yes/no)
- Extralymphatic and extraosseal tissue infiltration or pathologic mass (yes/no)

❖ FDG-PET (CT)

- FDG-PET (CT) activity (selection)
  - ND
  - negative

        - 1 osteolytic lesion
        - 2 osteolytic lesions
        - more than 2 lesions
        - accelerated osteoporosis
    - Abdominal nodal or extranodal activity (yes/no)
    - Thoracic nodal or extranodal activity (yes/no)
    - Extraabdominal and extrathoracic activity (yes/no)
- Laboratory examination before therapy
    - M-protein type (selection)
        - IgM Kappa
        - IgM Lambda
    - Serum M-protein quantity (g/l) (real number - scale: 1)
    - Serum FLC quantity measured (yes/no)
    - Serum free lambda quantity (mg/l) (real number - scale: 0)
    - Serum free kappa quantity (mg/l) (real number - scale: 0)
    - Kappa/lambda ratio (real number - scale: 0) *computed*
    - Urine M-protein quantity (mg/24h) (real number - scale: 1)
    - Urine M-protein quantity (mg/l) (real number - scale: 2)
- Polyclonal immunoglobulin quantitative estimation
    - IgM quantity (g/l) (real number - scale: 0)
    - IgA quantity (g/l) (real number - scale: 0)
    - IgG quantity (g/l) (real number - scale: 0)
    - Date of sample collection (HLC) (date)
    - Ig kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
    - Ig lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
    - HLC ratio (real number - scale: 2) *abs. min:0 computed read-only*
- Laboratory analysis results before therapy
    - Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
    - Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
    - Leukocyte count (10E9/l) (real number - scale: 0)
    - Neutrofil count (10E9/l) (real number - scale: 0)
    - Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
    - Albumin level (g/l) (real number - scale: 0) *abs. min:0*
    - Total protein (g/l) (real number - scale: 0)
    - Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*

- Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
- LDH (ukat/l) (real number - scale: 0) *abs. min:0*
- Upper normal value of LDH (ukat/l) (real number - scale: 0)
- LDH/upper normal value of LDH (real number - scale: 2) *computed*
- CRP (mg/l) (real number - scale: 0) *abs. min:0*
- Cholesterol (mmol/l) (real number - scale: 2)
- Plasma viscosity (selection)
  - ND
  - no
  - yes
- Plasma viscosity (real number - scale: 0)
- Kryoglobulinemia (selection)
  - ND
  - no
  - yes
- Cold aglutinins (selection)
  - ND
  - no
  - yes
- Antierytrocytic antibody (selection)
  - ND
  - no
  - yes
- Antitrombocytic antibody (selection)
  - ND
  - no
  - yes
- AL-amyloidosis histologic confirmation (selection)
  - ND
  - no
  - yes

❖ <u>Cytogenetic</u>

❖ <u>Cytogenetic</u>

- Cytogenetic examination (yes/no)
- Del 6q (yes/no)

- Del 6q (%) (real number - scale: 0)
- Translocation on chromosome 14, locus IgH (yes/no)

❖ Molecular-biology

- Molecular-biology examination (yes/no)
- MYD88 examination (yes/no)
- Mutation in MYD88 gene (selection)
  - negative
  - L265P
- CXCR4 examination (yes/no)
- Mutation in CXCR4 gene (selection)
  - negative
  - nonsense
  - frameshift
- Specify mutation type in CXCR4 gene (string)

WM - treatment

❖ Primary treatment

- Treatment modality (selection)
  - Corticosteroids only
  - Alkylation cytostatics +- corticosteroids
  - CHOP
  - R-CHOP
  - Fludarabine only
  - Fludarabine with alkylation cytostatics
  - 2-chlordeoxyadenosine only
  - 2-chlordeoxyadenosine with alkylation cytostatics
  - Anti-CD20 antibody monotherapy
  - Anti-CD20 antibody with alkylations drug
  - Anti-CD20 antibody with fludarabine
  - Anti-CD20 antibody with fludarabin and alkylations drug
  - Anti-CD20 antibody with 2-chlordeoxyadenosine
  - Anti-CD20 antibody with 2-chlordeoxyadenosine and alkylations drug
  - Thalidomide and dexamethasone
  - Cyclophosphamide thalidomide and dexametasone
  - Bortezomib monotherapy

        - Bortezomib in combination with anti-CD20 +- glukocorticoids
        - Bortezomib in combination with doxorubicin +-glucokorticoids
        - Bortezomib in combination with cyclophosphamide and dexamethasone (CVD)
        - High dose therapy with autolologous transpantation
        - High dose therapy with allogeneic transplantation
        - Other
    - Other therapy (string)
    - Plasmapheresis (selection)
        - Yes
        - No
        - Unknown
    - Number of plasmapheresis sessions (number)
    - Date of treatment beginning (date) *abs. min:"1.1.1900"*
    - Number of therapy cycles (number) *abs. min:0*
    - Last cycle date of this line of therapy (date)
- <u>Therapeutic response</u>
    - Serum M-protein entry level (g/l) (real number - scale: 0) *abs. min:0*
    - Serum M-protein level after treatment (g/l) (real number - scale: 0) *abs. min:0*
    - Serum M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
    - The best therapeutic response (serum M protein g/l) (real number - scale: 2)
    - The date of the best therapeutic response (date)
    - The date of the 50% decrease of paraprotein and fullfilling other criteria of PR (date)
    - Immunofixation after treatment - serum (selection)
        - NA
        - negative
        - positive
    - Bone marrow evaluation at the best therapeutic response (selection)
        - ND
        - Normal
        - Pathological
    - Number of lymfoplasmocytic cells (real number - scale: 0)
    - IgG after therapy (g/l) (real number - scale: 2)
    - IgA after therapy (g/l) (real number - scale: 2)
    - IgM after therapy (g/l) (real number - scale: 2)

- CT examination of thorax and abdomen at the time of best laboratory response (yes/no)
- Lymphadenopathy (yes/no)
- Hepatomegaly (yes/no)
- Splenomegaly (yes/no)
- Sonographic examination at the time of the best laboratory response (yes/no)
- Lymphadenopathy inguinal (yes/no)
- Lymphadenopathy abdominal (yes/no)
- Lymphadenopathy axillar (yes/no)
- Lymphadenopathy cervical (neck) (yes/no)
- Hepatomegaly (yes/no)
- Splenomegaly (yes/no)
- Maximum response reached by the first line treatment (selection)
  - CR
  - PR
  - SD
  - PD

❖ Primary treatment adverse events

- SAE (Serious Adverse Events) ((yes/no)
- Description (long string)
- SUSAR (Suspect Serious Adverse Events) (yes/no)
- Description (long string)

❖ Relaps/progression

- Date of relaps of the disease from CR or date of progression from PR,SD (date)

WM Following treatment

❖ Line of treatment

- Line of treatment (number) *abs. min:0*

❖ Reason for the restart of the therapy

- Clinical symptoms of hyperviskosity (selection)
  - unknown
  - no
  - yes
- Clinical symptoms of cryoglobulinaemia (selection)
  - unknown
  - no

        - yes
    - Clinical symptoms of neuropathy (selection)
        - unknown
        - no
        - yes
    - Clinical symptoms of AK-amyloidosis (selection)
        - unknown
        - no
        - yes
    - B symptoms (selection)
        - unknown
        - no
        - yes
    - Cytopenia - haemoglobin < 100 g/l (selection)
        - unknown
        - no
        - yes
    - Cytopenia - trombocyte < 100E9 /l (selection)
        - unknown
        - no
        - yes
    - Bulky lymphadenopathy (selection)
        - unknown
        - no
        - yes
    - Organomegaly (selection)
        - unknown
        - no
        - yes
    - Other (selection)
        - unknown
        - no
        - yes
    - Other specification (string)
- <u>Treatment</u>

- Treatment modality (selection)
  - Corticosteroids only
  - Alkylation cytostatics +- corticosteroids
  - CHOP
  - R-CHOP
  - Fludarabine only
  - Fludarabine with alkylation cytostatics
  - 2-chlordeoxyadenosine only
  - 2-chlordeoxyadenosine with alkylation cytostatics
  - Anti-CD20 antibody monotherapy
  - Anti-CD20 antibody with alkylations drug
  - Anti-CD20 antibody with fludarabine
  - Anti-CD20 antibody with fludarabin and alkylations drug
  - Anti-CD20 antibody with 2-chlordeoxyadenosine
  - Anti-CD20 antibody with 2-chlordeoxyadenosine and alkylations drug
  - Thalidomide and dexamethasone
  - Cyclophosphamide thalidomide and dexametasone
  - Bortezomib monotherapy
  - Bortezomib in combination with anti-CD20 +- glukocorticoids
  - Bortezomib in combination with doxorubicin +-glucokorticoids
  - Bortezomib in combination with cyclophosphamide and dexamethasone (CVD)
  - High dose therapy with autolologous transpantation
  - High dose therapy with allogeneic transplantation
  - Other
- Other therapy (string)
- Plasmapheresis (selection)
  - Yes
  - No
  - Unknown
- Number of plasmapheresis sessions (number)
- Date of treatment beginning (date) *abs. min:"1.1.1900"*
- Number of therapy cycles (number) *abs. min:0*
- Last cycle date of this line of therapy (date)

❖ <u>Therapeutic response</u>

- Serum M-protein entry level (g/l) (real number - scale: 0) *abs. min:0*

- Serum M-protein level after treatment (g/l) (real number - scale: 0) *abs. min:0*
- Serum M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
- The best therapeutic response (serum M protein g/l) (real number - scale: 2)
- The date of the best therapeutic response (date)
- Immunofixation after treatment - serum (selection)
  - NA
  - negative
  - positive
- Immunofixation at the best therapeutic response (selection)
  - NA
  - negative
  - positive

❖ <u>CT examination</u>

- CT examination of thorax and abdomen at the time of best laboratory response (yes/no)
- Lymphadenopathy (yes/no)
- Hepatomegaly (yes/no)

❖ <u>Sonographic examination</u>

- Sonographic examination at the time of the best laboratory response (yes/no)
- Lymphadenopathy inguinal (yes/no)
- Lymphadenopathy abdominal (yes/no)
- Lymphadenopathy axillar (yes/no)
- Lymphadenopathy cervical (neck) (yes/no)

❖ <u>-</u>

- Bone marrow evaluation at the best therapeutic response (selection)
  - ND
  - Normal
  - Pathological
- Number of lymfoplasmocytic cells (real number - scale: 0)
- Maximum response for treatment of relaps (selection)
  - CR
  - PR
  - SD
  - PD
- The date of the 50% decrease of paraprotein and fullfilling other criteria of PR (date)

- Date of relaps of the disease from CR or date of progression from PR,SD (date)

❖ Adverse events

- SAE (Serious Adverse Events) (yes/no)
- Description (long string)
- SUSAR (Suspect Serious Adverse Events) (yes/no)
- Description (long string)

WM Follow up

❖ Follow up

- Date of evaluation (date)
- Patient (selection)
  - unknown
  - alive
  - dead
- Patient status (selection)
  - unknown
  - treated
  - not treated
- Transformation of MW (yes/no)
- Date of transformation (date)
- Specify (string)
- Other malignant disease (yes/no)
- Specify disease (string)
- Date of death (date)
- Cause of death (selection)
  - Related to diagnosis MW
  - Related to tranformation of MW
  - Related to the other malignant disease
  - Not related to malignant disease

FISH

❖ Sample

- Date of sample collection (dd.mm.yyyy) (date)
- Sample ID (string)
- Sample type (selection)

        - DB
        - SB
        - F
        - FS
    - Therapy (selection)
        - Relapse before V
        - Relapse before T
        - Relapse before R
        - New Dg. before V
        - New Dg. before T
        - New Dg. before R
        - Relapse
        - New Dg.
        - After T
        - After V
        - After R
        - Before T
        - Before V
        - Before R
    - Date of sample processing (dd.mm.yyyy) (date)
    - Purity of the sample (Plasma cell infiltration) (%) (real number - scale: 2) *abs. min:0 abs. max:100*
    - Cellularity CD138+ Fraction: [x 10E6 Cells] (real number - scale: 2)
- <u>FISH</u>
    - FISH evaluated (yes/no)
    - Reason for not evaluating (selection)
        - Low purity
        - Low cellurarity
        - No plasma cells
        - Contamination
        - Insufficient amout of suspension
        - Insufficient amount of slides after FACS
        - Other
    - Other reason (string)
- <u>FISH test results</u>
- <u>Deletion 13q14 (RB1 gene)</u>

- Number of evaluated cells (number) *abs. min:0*
- Positive examination finding (%) (real number - scale: 2) *abs. min:0 abs. max:100*
- FISH examination (selection)
  - Not assessable
  - Deletions 13q14
  - Monosomy 13
  - Other
- Other finding of examination (string)
- Code (selection)
  - P
  - N

❖ <u>Deletion 17p13</u>

- Number of evaluated cells (number) *abs. min:0*
- Positive examination finding (%) (real number - scale: 2) *abs. min:0 abs. max:100*
- FISH examination finding (selection)
  - Not assessable
  - Deletions 17p13
  - Monosomy 17
  - Other
- Other examination finding (string)
- Code (selection)
  - P
  - N

❖ <u>Translocation t(4;14)</u>

- Number of evaluated cells (number) *abs. min:0*
- Positive examination finding (%) (real number - scale: 2) *abs. min:0 abs. max:100*
- FISH examination finding (selection)
  - Not assessable
  - t(4;14)
  - Fusion
  - Other
- Other examination finding (string)
- Code (selection)
  - P
  - N

- Gain 1q21
  - Number of evaluated cells (number) *abs. min:0*
  - Positive examination finding (%) (real number - scale: 2) *abs. min:0 abs. max:100*
  - FISH examination finding (selection)
    - Not assessable
    - Gain 1q21
    - Trisomy 1
    - Other
  - Other examination finding (string)
  - Most frequent examination finding (string)
  - Code taking into account the 20% cut-off (selection)
    - P
    - N
- Hyperdiploidy
  - Number of evaluated cells (number) *abs. min:0*
  - Positive examination finding (%) (real number - scale: 2) *abs. min:0 abs. max:100*
  - FISH examination finding (selection)
    - Not assessable
    - Hyperdiploidy
    - Nonhyperdiploidy
    - Other
  - Other examination finding (string)
  - Code (selection)
    - P
    - N
- Report
  - Report published (yes/no)
  - Report issued on (dd.mm.yyyy) (date)

Primary treatment - switch

- Biochemistry before treatment
  - Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
  - Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
  - Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
  - Albumin level (g/l) (real number - scale: 0) *abs. min:0*

- Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*
- Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
- LDH (ukat/l) (real number - scale: 0) *abs. min:0*
- CRP (mg/l) (real number - scale: 0) *abs. min:0*

❖ <u>Before treatment</u>

- Status Performance (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
- Karnofsky status (selection)
  - NA
  - 10
  - 20
  - 30
  - 40
  - 50
  - 60
  - 70
  - 80
  - 90
  - 100
- Durie-Salmon stage (selection)
  - I
  - II
  - III
- Substage (selection) *computed*
  - A
  - B
- ISS classification (selection) *computed*
  - Stage 1
  - Stage 2
  - Stage 3
- Change of M-protein type? (yes/no)

- M-protein type (selection)
  - IgG
  - IgA
  - IgD
  - IgE
  - IgM
  - Biclonal
  - Triclonal
  - Nonsecretory
  - LC only
- Light chain type (selection)
  - kappa
  - lambda
  - biclonal
- Serum M-protein entry level (g/l) (real number - scale: 0) *abs. min:0*
- Urine M-protein entry level (mg/24h) (real number - scale: 0) *abs. min:0*
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion

- 2 osteolytic lesions
- more than 2 lesions
- accelerated osteoporosis
- can not evaluate

- Osteolytic lesions - PET (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET/CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - MIBI (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Extramedullary mass (yes/no)
- Extramedullary mass - relation (selection)
  - extramedullary mass NOT related to bone
  - bone related extramedullary tumor mass
  - both tips
- Extramedullary mass histology (selection)
  - NA

        - negative
        - positive
    - Extramedullary masses count (selection)
        - 1
        - 2
        - 3
        - more than 3
    - Max size (cm) x (real number - scale: 0) *abs. min:0*
    - Max size (cm) y (real number - scale: 0) *abs. min:0*
    - Mass area (cm2) (real number - scale: 0) *abs. min:0 computed*
    - Bone marrow aspiration cytology (selection)
        - NOT DONE
        - negative
        - positive
    - Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*
    - Bone marrow histology (selection)
        - NOT DONE
        - negative
        - positive
    - Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*
- <u>Cytogenetics (FISH) before treatment</u>
    - Cytogenetics (yes/no)
    - Sample date (date) *abs. min:"1.1.1900"*
- <u>Treatment</u>
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
    - Combined with (selection)
        - No
        - Thalidomid

        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
    - Health insurance company (selection)
        - 111 - Všeobecná zdravotní pojišťovna
        - 201 - Vojenská zdravotní pojišťovna
        - 205 - Česká průmyslová zdravotní pojišťovna
        - 207 - Oborová pojišťovna zaměstnanců bank, pojišťoven a stavebnictví
        - 209 - Zaměstnanecká pojišťovna Škoda
        - 211 - Zdravotní pojišťovna Ministerstva vnitra ČR
        - 213 - Revírní bratrská pokladna
        - 217 - Zdravotní pojišťovna METAL-ALIANCE - do 1.10.2012
        - 222 - Česká národní zdravotní pojišťovna - do 1.10.2009
        - 227 - AGEL - do 1.7.2009
        - 228 - MÉDIA - do 28.3.2011
        - 999 - Není pojištěncem české ZP
    - Clinical study (yes/no)
    - Treatment (switch) beginning date (date) *abs. min: 1.1.1900*
    - Length of cycle (number) *abs. min:0*
    - Number of administrations per cycle (number) *abs. min:0*
    - Dosage of the first administration (mg) (real number - scale: 2) *abs. min:0*
    - Dosage of the first administration (mg/m2) (real number - scale: 2) *abs. min:0*
    - Route of administration (selection)
        - only subcutaneous
        - only intravenous
        - subcutaneous and change to intravenous
        - intravenous and change to subcutaneous
    - Number of cycles (real number - scale: 2) *abs. min:0*
    - Total number of administrations (number) *abs. min:0*
    - Total cumulative dose (mg) (real number - scale: 2) *abs. min:0*
- <u>Second drug for drug combination (for switch data see section below)</u>
    - Dosage of the first administration (mg) - second drug (real number - scale: 2) *abs. min:0*

- Dosage of the first administration (mg/m2) - second drug (real number - scale: 2) *abs. min:0*
- Route of administration - second drug (selection)
  - only subcutaneous
  - only intravenous
  - subcutaneous and change to intravenous
  - intravenous and change to subcutaneous
- Number of administrations per cycle - second drug (number) *abs. min:0*
- Total number of administrations - second drug (number) *abs. min:0*
- Total cumulative dose (mg) - second drug (real number - scale: 2) *abs. min:0*
- Reason for treatment withdrawal (selection)
  - Treatment response
  - Treatment response + PBSCT (transplantation)
  - According treatment protocol
  - Insufficient response
  - Progression
  - Toxicity
  - Exitus
  - Other
- Specify other reason (string)
- MR after cycle (number) *abs. min:0*
- Date of MR (date) *abs. min:"1.1.1900"*
- PR after cycle (number) *abs. min:0*
- Date of PR (date) *abs. min:"1.1.1900"*
- VGPR after cycle (number) *abs. min:0*
- Date of VGPR (date) *abs. min:"1.1.1900"*
- CR after cycle (number) *abs. min:0*
- Date of CR (date) *abs. min:"1.1.1900"*
- Response before transplant (selection)
  - PG
  - SD
  - PR
  - VGPR
  - CR
  - sCR
  - MR

        - NA
    - Dose reduction (yes/no)
    - Interruption of treatment (yes/no)
- Dose reduction
    - Reduction number (selection)
        - 1st
        - 2nd
        - 3rd
        - 4th
        - 5th
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
    - 1st reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
        - other
    - Specify other (string)
    - Grade (selection)
        - 0
        - 1

- 2
- 3
- 4
- 5

- 2nd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 3rd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia

- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- New dosage (mg) (real number - scale: 2) *abs. min:0*
- New dosage (mg/m2) (real number - scale: 2) *abs. min:0*

❖ <u>Interruption of treatment</u>

- Interruption number (selection)
  - 1st
  - 2nd
  - 3rd
  - 4th
  - 5th
- Drug (selection)
  - Thalidomid
  - Velcade
  - Revlimid
  - Bendamustin
  - Imnovid
  - Carfilzomib
  - Ixazomib
  - All
- 1st reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia

    - Neutropenia
    - Anemia
    - other
- Specify other (string)
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 2nd reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea
    - Constipation
    - Fatigue
    - Thrombosis/thrombus/Embolism
    - Infection
    - Thrombocytopenia
    - Neutropenia
    - Anemia
- Grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
    - 5
- 3rd reason (selection)
    - Neuropathy
    - Nausea, vomiting
    - Anorexia
    - Diarrhoea

        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5

❖ Toxicity

❖ Toxicity before treatment

- Grade of thrombocytopenia before treatment (selection)
    - 0
    - 1
    - 2
    - 3
    - 4
- Grade of neuropathy before treatment (selection)
    - 0
    - 1
    - 2
    - 3
    - 4

❖ Toxicity during treatment

- Neuropathy - grade (selection)
    - 0
    - 1
    - 2
    - 3
    - 4

- 5
- ND

- Nausea, vomiting - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Anorexia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Diarrhoea - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Constipation - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Fatigue - grade (selection)

- 0
- 1
- 2
- 3
- 4
- 5
- ND

- Thrombosis/thrombus/Embolism - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Infection - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Thrombocytopenia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Neutropenia - grade (selection)
  - 0
  - 1
  - 2

        - 3
        - 4
        - 5
        - ND
    - Anemia - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
        - ND
    - Other - text (string)
    - Other - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Other 2 - text (string)
    - Other 2 - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Switch of treatment due to toxicity (yes/no)
- <u>Anticoagulant treatment</u>
    - Anticoagulant treatment (yes/no)
    - Type of anticoagulant treatment (selection)
        - aspirin
        - warfarin
        - LMWH

        - other
    - Specify anticoagulant treatment (string)
- Hemopoetic growth factor
    - Hemopoetic growth factor (yes/no)
    - Dosage 30 IU / 0,5ml - number of doses (number) *default abs. min:0*
    - Dosage 48 IU/0,5 ml - number of doses (number) *default abs. min:0*
- Comments
    - Comments (long string)

Following treatment - switch

- Biochemistry before treatment
    - Hemoglobin level (g/l) (real number - scale: 0) *abs. min:0*
    - Thrombocyte count (10E9/l) (real number - scale: 1) *abs. min:0*
    - Calcium total level (mmol/l) (real number - scale: 0) *abs. min:0*
    - Albumin level (g/l) (real number - scale: 0) *abs. min:0*
    - Creatinine level (umol/l) (real number - scale: 0) *abs. min:0*
    - Beta2 microglobulin (mg/l) (real number - scale: 0) *abs. min:0*
    - LDH (ukat/l) (real number - scale: 0) *abs. min:0*
    - CRP (mg/l) (real number - scale: 0) *abs. min:0*
- Before treatment
    - Status Performance (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
    - Karnofsky status (selection)
        - NA
        - 10
        - 20
        - 30
        - 40
        - 50
        - 60
        - 70

- 80
- 90
- 100

- Durie-Salmon stage (selection)
  - I
  - II
  - III
- Substage (selection) *computed*
  - A
  - B
- ISS classification (selection) *computed*
  - Stage 1
  - Stage 2
  - Stage 3
- Change of M-protein type? (yes/no)
- M-protein type (selection)
  - IgG
  - IgA
  - IgD
  - IgE
  - IgM
  - Biclonal
  - Triclonal
  - Nonsecretory
  - LC only
- Light chain type (selection)
  - kappa
  - lambda
  - biclonal
- Osteolytic lesions X-ray (selection)
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2
  - accelerated osteoporosis

- can not evaluate

- Osteolytic lesions - NMR (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - PET/CT (selection)
  - ND
  - negative
  - 1 osteolytic lesion
  - 2 osteolytic lesions
  - more than 2 lesions
  - accelerated osteoporosis
  - can not evaluate
- Osteolytic lesions - MIBI (selection)
  - ND

    - negative
    - 1 osteolytic lesion
    - 2 osteolytic lesions
    - more than 2 lesions
    - accelerated osteoporosis
    - can not evaluate
- Extramedullary mass (yes/no)
- Extramedullary mass - relation (selection)
    - extramedullary mass NOT related to bone
    - bone related extramedullary tumor mass
    - both tips
- Extramedullary mass histology (selection)
    - NA
    - negative
    - positive
- Extramedullary masses count (selection)
    - 1
    - 2
    - 3
    - more than 3
- Max size (cm) x (real number - scale: 0) *abs. min:0*
- Max size (cm) y (real number - scale: 0) *abs. min:0*
- Mass area (cm2) (real number - scale: 0) *abs. min:0 computed*
- Serum M-protein entry level (g/l) (real number - scale: 0) *abs. min:0*
- Urine M-protein entry level (mg/24h) (real number - scale: 0) *abs. min:0*
- Bone marrow aspiration cytology (selection)
    - NOT DONE
    - negative
    - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*
- Bone marrow histology (selection)
    - NOT DONE
    - negative
    - positive
- Plasmocyte count M (%) (real number - scale: 0) *abs. min:0 abs. max:100*

- Cytogenetics before treatment
  - Cytogenetics (yes/no)
  - Sample date (date) *abs. min:"1.1.1900"*
- Treatment
  - Drug (selection)
    - Thalidomid
    - Velcade
    - Revlimid
    - Bendamustin
    - Imnovid
    - Carfilzomib
    - Ixazomib
  - Combined with (selection)
    - No
    - Thalidomid
    - Velcade
    - Revlimid
    - Bendamustin
    - Imnovid
    - Carfilzomib
    - Ixazomib
  - Health insurance company (selection)
    - 111 - Všeobecná zdravotní pojišťovna
    - 201 - Vojenská zdravotní pojišťovna
    - 205 - Česká průmyslová zdravotní pojišťovna
    - 207 - Oborová pojišťovna zaměstnanců bank, pojišťoven a stavebnictví
    - 209 - Zaměstnanecká pojišťovna Škoda
    - 211 - Zdravotní pojišťovna Ministerstva vnitra ČR
    - 213 - Revírní bratrská pokladna
    - 217 - Zdravotní pojišťovna METAL-ALIANCE - do 1.10.2012
    - 222 - Česká národní zdravotní pojišťovna - do 1.10.2009
    - 227 - AGEL - do 1.7.2009
    - 228 - MÉDIA - do 28.3.2011
    - 999 - Není pojištěncem české ZP
  - Clinical study (yes/no)

- Treatment (switch) beginning date (date) *abs. min:"1.1.1900"*
- Date of transplant (date) *abs. min:"1.1.1900"*
- Special transplantation technique (selection)
  - Tandem autotransplantation
  - Full - Allogenic transplantation
  - Mini - Allogenic transplantation
  - No
- Date of subsequent transplant (date) *abs. min:"1.1.1900"*
- Length of cycle (number) *abs. min:0*
- Dosage of the first administration (mg) (real number - scale: 2) *abs. min:0*
- Dosage of the first administration (mg/m2) (real number - scale: 2) *abs. min:0*
- Route of administration (selection)
  - only subcutaneous
  - only intravenous
  - subcutaneous and change to intravenous
  - intravenous and change to subcutaneous
- Number of administrations per cycle (number) *abs. min:0*
- Number of cycles (real number - scale: 2) *abs. min:0*
- Total number of administrations (number) *abs. min:0*
- Total cumulative dose (mg) (real number - scale: 2) *abs. min:0*

❖ <u>Second drug for drug combination</u>

- Dosage of the first administration (mg) - second drug (real number - scale: 2) *abs. min:0*
- Dosage of the first administration (mg/m2) - second drug (real number - scale: 2) *abs. min:0*
- Route of administration – second drug (selection)
  - only subcutaneous
  - only intravenous
  - subcutaneous and change to intravenous
  - intravenous and change to subcutaneous
- Number of administrations per cycle - second drug (number) *abs. min:0*
- Total number of administrations - second drug (number) *abs. min:0*
- Total cumulative dose (mg) - second drug (real number - scale: 2) *abs. min:0*
- Reason for treatment withdrawal (selection)
  - Treatment response
  - Treatment response + PBSCT (transplantation)

    - According treatment protocol
    - Insufficient response
    - Progression
    - Toxicity
    - Exitus
    - Other
- Specify other reason (string)
- Serum M-protein level after treatment (g/l) (real number - scale: 0) *abs. min:0*
- Urine M-protein level after treatment (mg/24h) (real number - scale: 0) *abs. min:0*
- Serum M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
- Urine M-protein - ratio after treatment/entry (%) (real number - scale: 1) *abs. min:0 computed*
- Immunofixation after treatment - serum (selection)
    - NA
    - negative
    - positive
- Immunofixation after treatment - urine (selection)
    - NA
    - negative
    - positive
- MR after cycle (number) *abs. min:0*
- Date of MR (date) *abs. min:"1.1.1900"*
- PR after cycle (number) *abs. min:0*
- Date of PR (date) *abs. min:"1.1.1900"*
- VGPR after cycle (number) *abs. min:0*
- Date of VGPR (date) *abs. min:"1.1.1900"*
- CR after cycle (number) *abs. min:0*
- Date of CR (date) *abs. min:"1.1.1900"*
- Response before transplant (selection)
    - PG
    - SD
    - PR
    - VGPR
    - CR
    - sCR

        - MR
        - NA
    - Dose reduction (yes/no)
    - Interruption of treatment (yes/no)
- <u>Dose reduction</u>
    - Reduction number (selection)
        - 1st
        - 2nd
        - 3rd
        - 4th
        - 5th
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
    - 1st reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
        - other
    - Specify other (string)
    - Grade (selection)
        - 0

- 1
- 2
- 3
- 4
- 5

- 2nd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 3rd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia

        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - New dosage (mg) (real number - scale: 2) *abs. min:0*
    - New dosage (mg/m2) (real number - scale: 2) *abs. min:0*
- <u>Interruption of treatment</u>
    - Interruption number (selection)
        - 1st
        - 2nd
        - 3rd
        - 4th
        - 5th
    - Drug (selection)
        - Thalidomid
        - Velcade
        - Revlimid
        - Bendamustin
        - Imnovid
        - Carfilzomib
        - Ixazomib
        - All
    - 1st reason (selection)
        - Neuropathy
        - Nausea, vomiting
        - Anorexia
        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection

- Thrombocytopenia
- Neutropenia
- Anemia
- other

- Specify other (string)
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 2nd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia
  - Diarrhoea
  - Constipation
  - Fatigue
  - Thrombosis/thrombus/Embolism
  - Infection
  - Thrombocytopenia
  - Neutropenia
  - Anemia
- Grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
- 3rd reason (selection)
  - Neuropathy
  - Nausea, vomiting
  - Anorexia

        - Diarrhoea
        - Constipation
        - Fatigue
        - Thrombosis/thrombus/Embolism
        - Infection
        - Thrombocytopenia
        - Neutropenia
        - Anemia
    - Grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
- Toxicity
    - Grade of thrombocytopenia before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
    - Grade of neuropathy before treatment (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
    - Neuropathy - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5

- ND

- Nausea, vomiting - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Anorexia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Diarrhoea - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Constipation - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Fatigue - grade (selection)
  - 0

- 1
- 2
- 3
- 4
- 5
- ND

- Thrombosis/thrombus/Embolism - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Infection - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Thrombocytopenia - grade (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - ND
- Neutropenia - grade (selection)
  - 0
  - 1
  - 2
  - 3

        - 4
        - 5
        - ND
    - Anemia - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
        - ND
    - Other - text (string)
    - Other - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Other 2 - text (string)
    - Other 2 - grade (selection)
        - 0
        - 1
        - 2
        - 3
        - 4
        - 5
    - Switch of treatment due to toxicity (yes/no)
- <u>Anticoagulant treatment</u>
    - Anticoagulant treatment (yes/no)
    - Type of anticoagulant treatment (selection)
        - aspirin
        - warfarin
        - LMWH
        - other

- Specify anticoagulant treatment (string)

❖ Hemopoetic growth factor

- Hemopoetic growth factor (yes/no)
- Dosage 30 IU / 0,5ml - number of doses (number) *default abs. min:0*
- Dosage 48 IU/0,5 ml - number of doses (number) *default abs. min:0*

❖ Comments

- Comments (long string)

AMYL - diagnostics

❖ Characteristic of amyloidosis

- Date of diagnosis (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
- Type of amyloidosis (selection)
  - Systemic
  - Localized

❖ Localization

- Node (checkbox)
- GIT (checkbox)
- Tracheobronchial (checkbox)
- Pulmonary (checkbox)
- Diffused (checkbox)
- Nodular (checkbox)
- Other (checkbox)
- Specify (string)

❖ Labratory - serum (protein analysis)

- M-protein type (selection)
  - IgG
  - IgA
  - IgD
  - IgE
  - IgM
  - Biclonal
  - Triclonal
  - Nonsecretory
  - LC only
- Light chain type (selection)

- Kappa
- Lambda
- Biclonal

- Serum M-protein quantity (g/l) (real number - scale: 2) *abs. min:0*
- Total protein (g/l) (real number - scale: 2) *abs. min:0*
- Albumin level (g/l) (real number - scale: 2) *abs. min:0*
- Serum kappa FLC quantity (mg/l) (real number - scale: 2) *abs. min:0*
- Serum lambda FLC quantity (mg/l) (real number - scale: 2) *abs. min:0*
- Kappa/lambda ratio (real number - scale: 2) *computed*
- Polyclonal IgG quantity (g/l) (real number - scale: 2) *abs. min:0*
- Polyclonal IgA quantity (g/l) (real number - scale: 2) *abs. min:0*
- Polyclonal IgM quantity (g/l) (real number - scale: 2) *abs. min:0*
- IgG kappa HLC pair (g/l) (real number - scale: 2)
- IgG lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- IgG HLC ratio (real number - scale: 2) *computed*
- IgA kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- IgA lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- IgA HLC ratio (real number - scale: 2) *computed*
- IgM kappa HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- IgM lambda HLC pair (g/l) (real number - scale: 2) *abs. min:0*
- IgM HLC ratio (real number - scale: 2) *computed*

❖ <u>Analysis of a heart indicators</u>

- Troponin T (ug/l) (real number - scale: 3) *abs. min:0*
- NT-proBNP (ng/l) (real number - scale: 2) *abs. min:0*
- Mayo stage (selection) *computed*
  - Stage I
  - Stage II
  - Stage III
- Revised Mayo stage (selection) *computed*
  - Stage I
  - Stage II
  - Stage III
  - Stage IV

❖ <u>Other parameters</u>

- Hemoglobin level (g/l) (real number - scale: 2) *abs. min:0*

- Thrombocyte count (10E9/l) (real number - scale: 2) *abs. min:0*
- Factor X deficit (yes/no)
- Creatinine level (umol/l) (real number - scale: 2) *abs. min:0*
- Uric acid level (umol/l) (real number - scale: 2) *abs. min:0*
- Glom. filtration according to MDRD (ml/s/1,73m2) (real number - scale: 2) *abs. min:0*
- Beta2 microglobulin (mg/l) (real number - scale: 2) *abs. min:0*
- LDH (ukat/l) (real number - scale: 2) *abs. min:0*
- ALP (ukat/l) (real number - scale: 2) *abs. min:0*

❖ <u>Analysis of urine</u>

- Total protein in the urine (g/day) (real number - scale: 2) *abs. min:0*
- Urine M-protein type (selection)
  - IgA
  - IgG
  - IgD
  - IgM
  - Without complete Ig moleculs
- BJ urie type (selection)
  - Kappa
  - Lambda
  - Unknown
- Urine M-protein quantity (mg/24h) (real number - scale: 2) *abs. min:0*
- Urine albumin level (mg/24 h) (real number - scale: 2) *abs. min:0*

❖ <u>Bone marrow analysis</u>

- Plasmocyte count (%) in aspiration (real number - scale: 1) *abs. min:0 max:100*
- Plasmocyte count (%) in histology (real number - scale: 1) *abs. min:0 max:100*
- Clonal plasma cells count (%) in histology (real number - scale: 1) *abs. min:0 max:100*
- Flowcytometry (yes/no)
- Normal PC - CD19 (%) (real number - scale: 1) *abs. min:0 max:100*
- Abnormal PC - CD 56 (%) (real number - scale: 1) *abs. min:0 max:100*
- Cytogenetics (yes/no)
- IGH disruption (selection)
  - Positive
  - Negative
  - NA
- t(11,14) (selection)

    - Positive
    - Negative
    - NA
- t(11;14) (%) (real number - scale: 1)
- t(4,14) (selection)
    - Positive
    - Negative
    - NA
- t(4;14) (%)(real number - scale: 1)
- t(6,14) (selection)
    - Positive
    - Negative
    - NA
- t(6;14) (%) (real number - scale: 1)
- t(16,14) (selection)
    - Positive
    - Negative
    - NA
- t(14;16) (%) (real number - scale: 1)
- del -13q /monosomy (selection)
    - Positive
    - Negative
    - NA
- del(q14)/monosomy 13 (%) (real number - scale: 1)
- amp 1q21 (selection)
    - Positive
    - Negative
    - NA
- gain 1q21 (%) (real number - scale: 1)
- del(17) (p13) (selection)
    - Positive
    - Negative
    - NA
- del(17)(p13) (%) (real number - scale: 1)
- Hyperdiploidy (yes/no)

- Echocardiography
  - Echocardiography (yes/no)
  - Left ventricular ejection fraction (%) (number) *abs. min:0 max:100*
  - Interventricular septum diastolic diameter (mm) (real number - scale: 2) *abs. min:0*
  - Left atrium diameter (mm) (real number - scale: 2) *abs. min:0*
  - Mitral regurgitation (yes/no)
- MRI of myocard
  - MR of myocard yes/no)
  - Left ventricular ejection fraction (%) (number) *abs. min:0 max:100*
  - Interventricular septum diastolic diameter (mm) (real number - scale: 2) *abs. min:0*
  - Delayed enhancement (selection)
    - Positive
    - Negative
  - Type of involvement (selection)
    - Diffuse subendocardial
    - Diffuse transmural
    - Patchy
    - Difficult to select the optimal inversion time
- ECG
  - ECG (yes/no)
  - Basic rhythm (selection)
    - Sinus
    - Fibrillation
    - Flutter
    - Stimulated
  - Ventricular rate (selection)
    - < 60/min
    - 60 - 100/min
    - > 100/min
  - Extrasystoles (selection)
    - SVES
    - KES
    - SVES + KES
    - Nezaznamenány
  - Low voltage of limb leads under 5 mm (yes/no)

- QS - "pseudoinfarct pattern" of anterior wall (yes/no)

❖ Abdominal ultrasound

- Liver width (cm) (real number - scale: 2) *abs. min:0*

❖ Characteristic of patient

- WHO status performance (selection)
  - 0
  - 1
  - 2
  - 3
  - 4
- Other serious diseases (not related with AL and damages of organs) (yes/no)
- Specify (string)
- Height (cm) (number) *abs. min:0 abs. max:250 min:120 max:220*
- Weight (kg) (number) *abs. min:0 abs. max:600 min:30 max:300*
- BMI (real number - scale: 2) *computed read-only*

❖ Characteristic of disease

- Nefrotic syndrome (yes/no)
- Heart failure (yes/no)
- NYHA (selection)
  - I
  - II
  - III
  - IV
- Orthostatic hypotension (yes/no)
- Peripheral neuropathy (yes/no)
- Hepatopathy (yes/no)
- GIT (yes/no)
- Skin (yes/no)

❖ Other signs

- Macroglossia (yes/no)
- Periorbital purpura (yes/no)
- Carpal Tunnel Syndrome (yes/no)
- Shoulder pad sign (yes/no)
- The total number of damaged organs (number) *abs. min:0*

❖ Amyloid positive biopsy

- Amyloid identified as AL (yes/no)
- Subcutaneous fat (selection)
  - Yes
  - No
  - Not done
- Tongue, buccal mucosa (selection)
  - Yes
  - No
  - Not done
- Rectum (selection)
  - Yes
  - No
  - Not done
- Bone marrow (selection)
  - Yes
  - No
  - Not done
- Kidney (selection)
  - Yes
  - No
  - Not done
- EMB (selection)
  - Yes
  - No
  - Not done
- Other (selection)
  - Yes
  - No
  - Not done
- Specify (string)

AMYL - Treatment

- Treatment
  - Line of therapy (selection)
    - 1st line

- 2nd line
- 3rd line
- 4th line

- Treatment beginning date (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
- Date of treatment withdrawal (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
- Regimen (selection)
  - Without treatment
  - Thalidomide based regimens
  - Velcade based regimens
  - Revlimid based regimens
  - Other regimens
  - Other conventional chemotherapy
  - Other induction followed by Autologous stem cell transplantation
  - Salvage autologous transplantation technique
  - Imnovid based regiment
  - Carfilzomib based regimen
  - Ixazomib based regimen
- Specifications (selection)
  - Without treatment
  - Thalidomide monotherapy
  - TD (Thalidomide + Dexamethasone)
  - TP (Thalidomide + Prednison)
  - CTD junior therapy (Cyclophosphamide+Thalidomide+Dexamethasone)
  - CTD senior therapy
  - MPT junior therapy (Melphalan + Prednisone + Thalidomide)
  - MPT senior therapy
  - VTD therapy (Velcade + Thalidomide + Dexamethasone)
  - CVTD therapy (Cyclophosphamide + Velcade + Thalidomide + Dexamethasone)
  - CTD induction followed by Autologous stem cell transplantation
  - CVTD induction followed by Autologous stem cell transplantation
  - VTD induction followed by Autologous stem cell transplantation
  - Other Thalidomide based combination
  - Other Thalidomid based induction followed by Autologous stem cell transplantation
  - TBD therapy (Thalidomide + Bendamustine + Dexamethasone)
  - TBP therapy (Thalidomide + Bendamustine + Prednison)

- Velcade monotherapy
- VD therapy (Velcade - Dexamethasone)
- VP therapy (Velcade + Prednison)
- CVD junior therapy (Cyclophosphamide + Velcade + Dexamethasone)
- CVD senior therapy
- VMP junior therapy (Velcade + Melphalan + Prednison)
- VMP senior therapy
- BDD therapy (Velcade + Adriamycin + Dexamethasone)
- RVD therapy induction (Revlimide + Velcade + Dexamethasone)
- VD induction followed by Autologous stem cell transplantation
- CVD induction followed by Autologous stem cell transplantation
- BDD induction followed by Autologous stem cell transplantation
- Other Velcade based combination
- Other Velcade based induction followed by Autologous stem cell transplantation
- BBD therapy (Velcade + Bendamustine + Dexamethasone)
- BBP therapy (Velcade + Bendamustine + Prednison)
- Revlimid monotherapy
- RP junior therapy (Revlimide + Prednisone)
- RP senior therapy
- RD therapy (Revlimide + Dexamethasone)
- RCD junior therapy (Revlimide + Cyclophosphamide + Dexamethasone)
- RCD senior therapy
- RP induction followed by Autologous stem cell transplantation
- RD induction followed by Autologous stem cell transplantation
- RCD induction followed by Autologous stem cell transplantation
- RVD induction followed by Autologous stem cell transplantation
- Other Revlimid based combination
- Other Revlimid based induction followed by Autologous stem cell transplantation
- RAD junior therapy (Revlimid-Adriamycin+ Dexamethasone)
- RAD senior therapy
- RAD induction followed by Autologous stem cell transplantation
- RBD therapy (Revlimide + Bendamustine + Dexamethasone)
- RBP therapy (Revlimide + Bendamustine + Prednison)
- RCD therapy (Revlimid + Carfilzomib + Dexamethason)
- RID therapy (Revlimid + Ixazomib + Dexamethason)

- Corticosteroid monotherapy
- Melphalan monotherapy
- Cyclophosphamide monotherapy
- MP therapy (Melphalan + Prednison)
- CP therapy (Cyclophosphamide + Prednison)
- CD therapy (Cyclophosphamide + Dexamethasone)
- VAD therapy (Vincristin + Adriamycin + Dexamethasone)
- VID therapy (Vincristin + Idarubicin + Dexamethason)
- CAD junior therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- CAD senior therapy
- CED therapy (Cyclophosphamide + Etoposide + Dexamethasone)
- VAD induction followed by Autologous stem cell transplantation
- VID induction followed by Autologous stem cell transplantation
- CAD induction followed by Autologous stem cell transplantation
- BD (Bendamustine + Dexamethazone)
- BP (Bendamustine + Prednison)
- Bendamustin monotherapy
- Other
- Other conventional chemotherapy
- Other induction followed by Autologous stem cell transplantation
- Salvage autologous transplantation technique
- Imnovid monotherapy
- Imnovid + Dexamethasone
- Other Imnovid based combination
- Carfilzomib monotherapy
- CD Therapy (Carfilzomib + Dexamethasone)
- CMP therapy (Carfilzomib + Melphalan + Prednison)
- Other Carfilzomid based combination
- Ixazomib monotherapy
- ID therapy (Ixazomib + Dexamethasone)
- LID therapy (Ixazomib + Lenalidomid + Dexamethasone)
- IMP therapy (Ixazomib + Melphalan + Prednison)
- Other Ixazomib based combination

- ASCT (yes/no)
- Dose of Mel (mg/m2) (real number - scale: 2) *abs. min:0*

- Response to treatment
  - Time since diagnosis to start of treatment (days) (real number - scale: 2) *computed read-only*
  - Final response to treatment (selection)
    - CR
    - VGPR
    - PR
    - SD
    - PD
  - Date of first treatment response (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
  - Date of maximal response (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
  - NT-proBNP (ng/l) in time of maximal response (real number - scale: 2) *abs. min:0*
  - TnT in time of maximal response (real number - scale: 2) *abs. min:0*
  - Level of proteinuria in time of maximal response (g/l/24 hod) (real number - scale: 2) *abs. min:0*
- Echocardiography
  - Echocardiography (yes/no)
  - Left ventricular ejection fraction (%) (number) *abs. min:0 max:100*
  - Interventricular septum diastolic diameter (mm) (real number - scale: 2) *abs. min:0*
  - Left atrium diameter (mm) (real number - scale: 2) *abs. min:0*
  - Mitral regurgitation (yes/no)
- Relapse/progression
  - Date of relapse/progression (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*

AMYL - Current status

- Current status
  - Date of last contact (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
  - Patient is dead (yes/no)
  - Date of death (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*

Amyloidosis with MM

- Characteristic of amyloidosis
  - Date of diagnosis (dd.mm.rrrr) (date) *abs. min:"1.1.1900"*
  - Type of amyloidosis (selection)
    - Systemic
    - Localized

- Localization
  - Node (checkbox)
  - GIT (checkbox)
  - Tracheobronchial (checkbox)
  - Pulmonary (checkbox)
  - Diffused (checkbox)
  - Nodular (checkbox)
  - Other (checkbox)
  - Specify (string)
- Labratory - serum (protein analysis)
  - Light chain type (selection)
    - Kappa
    - Lambda
    - Biclonal
  - Serum kappa FLC quantity (mg/l) (real number - scale: 2) *abs. min:0*
  - Serum lambda FLC quantity (mg/l) (real number - scale: 2) *abs. min:0*
- Analysis of a heart indicators
  - Troponin T (ug/l) (real number - scale: 3) *abs. min:0*
  - NT-proBNP (ng/l) (real number - scale: 2) *abs. min:0*
  - Mayo stage (selection) *computed*
    - Stage I
    - Stage II
    - Stage III
  - Revised Mayo stage (selection) *computed*
    - Stage I
    - Stage II
    - Stage III
    - Stage IV
- Other parameters
  - Factor X deficit (yes/no)
  - Uric acid level (umol/l) (real number - scale: 2) *abs. min:0*
  - Glom. filtration according to MDRD (ml/s/1,73m2) (real number - scale: 2) *abs. min:0*
  - ALP (ukat/l) (real number - scale: 2) *abs. min:0*
- Analysis of urine
  - Total protein in the urine (g/day) (59288) (real number - scale: 2) *abs. min:0*

- Urine M-protein type (selection)
  - IgA
  - IgG
  - IgD
  - IgM
  - Without complete Ig moleculs
- BJ urie type (selection)
  - Kappa
  - Lambda
  - Unknown
- Urine albumin level (mg/24 h) (real number - scale: 2) *abs. min:0*

❖ Echocardiography

- Echocardiography (yes/no)
- Left ventricular ejection fraction (%) (number) *abs. min:0 max:100*
- Interventricular septum diastolic diameter (mm) (real number - scale: 2) *abs. min:0*
- Left atrium diameter (mm) (real number - scale: 2) *abs. min:0*
- Mitral regurgitation (yes/no)

❖ MRI of myocard

- MR of myocard (yes/no)
- Left ventricular ejection fraction (%) (number) *abs. min:0 max:100*
- Interventricular septum diastolic diameter (mm) (real number - scale: 2) *abs. min:0*
- Delayed enhancement (selection)
  - Positive
  - Negative
- Type of involvement (selection)
  - Diffuse subendocardial
  - Diffuse transmural
  - Patchy
  - Difficult to select the optimal inversion time

❖ ECG

- ECG (yes/no)
- Basic rhythm (selection)
  - Sinus
  - Fibrillation
  - Flutter

        - Stimulated
    - Ventricular rate (selection)
        - < 60/min
        - 60 - 100/min
        - > 100/min
    - Extrasystoles (selection)
        - SVES
        - KES
        - SVES + KES
        - Nezaznamenány
    - Low voltage of limb leads under 5 mm (yes/no)
    - QS - "pseudoinfarct pattern" of anterior wall (yes/no)
- Abdominal ultrasound
    - Liver width (cm) (real number - scale: 2) *abs. min:0*
- Characteristic of patient
    - Other serious diseases (not related with AL and damages of organs) (yes/no)
    - Specify (string)
    - Height (cm) (number) *abs. min:0 abs. max:250 min:120 max:220*
    - Weight (kg) (number) *abs. min:0 abs. max:600 min:30 max:300*
    - BMI (real number - scale: 2) *computed read-only*
- Characteristic of disease
    - Nefrotic syndrome (yes/no)
    - Heart failure (yes/no)
    - NYHA (selection)
        - I
        - II
        - III
        - IV
    - Orthostatic hypotension (yes/no)
    - Peripheral neuropathy (yes/no)
    - Hepatopathy (yes/no)
    - GIT (yes/no)
    - Skin (yes/no)
- Other signs
    - Macroglossia (yes/no)

- Periorbital purpura (yes/no)
- Carpal Tunnel Syndrome (yes/no)
- Shoulder pad sign (yes/no)
- The total number of damaged organs (number) *abs. min:0*

❖ <u>Amyloid positive biopsy (25428)</u>

- Amyloid identified as AL (yes/no)
- Subcutaneous fat (selection)
  - Yes
  - No
  - Not done
- Tongue, buccal mucosa (selection)
  - Yes
  - No
  - Not done
- Rectum (selection)
  - Yes
  - No
  - Not done
- Bone marrow (selection)
  - Yes
  - No
  - Not done
- Kidney (selection)
  - Yes
  - No
  - Not done
- EMB (selection)
  - Yes
  - No
  - Not done
- Other (selection)
  - Yes
  - No
  - Not done
- Specify (string)